IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION : MDL NO. 2804

THIS DOCUMENT RELATES TO ALL CASES : CASE NO. 1:17-MD-2804

: Hon. Dan A. Polster

- - -

March 15, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of SCOTT D. TOMSKY taken pursuant to notice, was held at the offices of Golkow Litigation Services, One Liberty Place, 51st Floor, 1650 Market Street, Philadelphia, Pennsylvania, beginning at 9:31 a.m , on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Registered Merit Reporter and Notary Public.

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THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Bill Geigert. I'm a videographer for Golkow Litigation Services. Today's date is March 5, 2019 --

MS. HILLYER: 15.

THE VIDEOGRAPHER: Yeah, sorry. March 15, 2019, and the time is 9:31 a m.

This video deposition is being held in Philadelphia, Pennsylvania, in the matter of National Prescription Opioid Litigation, for the United States District Court, Northern District of Ohio, Eastern Division. The deponent is Scott Tomsky. Counsel will be noted on the stenographic record.

The court reporter is Ann Marie Mitchell, and she will now swear in the witness.

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SCOTT D. TOMSKY, after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. CRAWFORD:

Q. Good morning.

A. Good morning.

Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation.

Can you please state your full name?

A. Scott David Tomsky.

Q. And have you ever been deposed before?

A. Yes.

Q. How many times?

A. About a dozen.

Q. And so you know the rules pretty much.

It's you're under oath. Correct?

A. Correct.

Q. And you know, because we have to create a clean record, for me to finish my question and I should wait for you to finish your

answer so we're not talking over each other?

A. Yes.

Q. And if you don't understand a question, please feel free to ask me to clarify.

A. Yes.

Q. And you're welcome to take a break. If you need to take one, just let me know.

A. Okay.

Q. Can you please give me your home address?

A. Sure. [redacted]

Q. And who is your current employer?

A. Teva.

Q. What's the full name of your employer?

A. Teva USA.

Q. Is it -- is that the legal name of the company?

A. I'm not exactly sure or certain what the legal name of the company is.

Q. And what's your work address?

A. 425 Privet Road, Horsham,

Pennsylvania.
Q. And did you have any meetings to prepare for this deposition today?
A. Yes.
Q. And who did you meet with?
A. Teva counsel, Becca Hillyer.
Q. And was anyone else present?
A. There was another attorney. I don't remember her name.
Q. Was that at their offices here in Philly?
A. Yes.
Q. And how long did the meet -- how many meetings did you have?
A. Just one yesterday.
Q. And how long?
A. It was from 9:30 in the morning until roughly 3:00, 3:30 in the afternoon.
Q. And that was yesterday, you said?
A. Correct.
PHONE SPEAKER: I'm sorry to interrupt.
Would it be possible to move the microphone closer to the witness, please?

- - -
(A discussion off the record occurred.)
- - -
BY MR. CRAWFORD:
Q. Did you have any other meetings with anybody about the deposition?
A. No. There may have been a phone call, just asking me about my availability and the fact that I'd be asked to be deposed.
Q. And did you review any documents for this deposition?
A. Yes.
Q. About how many?
A. I don't know. A couple dozen.
Q. And generally what were they?
MS. HILLYER: I'll just -- I don't want him to get into the details of what they were. He can answer categorically so that doesn't get into the privilege.
BY MR. CRAWFORD:
Q. Go ahead.
A. Generally some emails, internal

reports and documents, presentations.
Q. How about, did you review any annual reports?
A. What kind of annual reports are you asking?
Q. To the FDA about your drugs.
A. No.
Q. How about approval letters or approval packets?
A. Approval letters.
Q. And for which drugs?
A. The buprenorphine/naloxone, primarily that product.
Q. And how -- general in your department, what's your current position at Teva?
A. So I'm vice president of North American generic regulatory affairs.
Q. And what's the name of your department at Teva?
A. Regulatory affairs.
Q. And who is your immediate superior?
A. Michael Banks.
Q. And what is his position?

A. He is in charge of global regulatory affairs.
Q. And who is his employer?
A. I'm not sure. I believe it's Teva UK.
Q. And is he based in the UK?
A. That's correct.
Q. And why are you reporting to somebody in the UK?
MS. HILLYER: Objection, calls for speculation.
THE WITNESS: I don't know. That's my boss when I joined the company, and it's who I've been reporting to since I joined.
BY MR. CRAWFORD:
Q. And he's -- he works for a different company than your company, though.
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. Is that correct?
A. I believe so.
Q. You think it's Teva UK.
Is there a full name for -- of

the company he works for?
A. I'm not certain.
Q. And who does Mr. Banks report to right now?
A. He reports to the global head of research and development.
Q. And who is that?
A. Her name is Hafrun. And her last name is Fridriksdottir.
Q. And where is Ms. Fridriksdottir located?
A. In Parsippany, New Jersey.
Q. And who is her employer?
A. I'm not certain.
Q. And do you have any opportunity to interact with Ms. Fridriksdottir?
A. Yes.
Q. On a pretty regular basis, I mean like at least once a week?
MS. HILLYER: Objection to form.
THE WITNESS: Yes. Regularly, once a week.
BY MR. CRAWFORD:
Q. And generally what comes to mind

as far as maybe the past month, what have your meetings been about with Ms. Fridriksdottir?
A. Status of applications.
Q. And do you have any responsibility -- first of all, let's go back.
Let's mark the first exhibit, which will be a LinkedIn profile.
- - -
(Deposition Exhibit No. Teva-Tomsky-1, Scott Tomsky LinkedIn Profile, 2 pages, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. We're going to flash the documents on the screen up here, and also I'll provide you with a copy.
A. Okay.
MS. HILLYER: This is LinkedIn?
MR. CRAWFORD: Yeah.
MS. HILLYER: Doesn't look like it.
MR. CRAWFORD: I actually figured out how to print a LinkedIn profile so it

doesn't look like it's from a web page. So you have to go to the little three dots next to the name, and that gives you an option.
MS. HILLYER: Good to know.
MR. CRAWFORD: Much cleaner.
BY MR. CRAWFORD:
Q. Does this look like generally what's on your LinkedIn page?
A. Generally, yes.
Q. And did you prepare this?
A. Yes.
Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America?
A. Correct.
Q. And is the rest of this information, just scanning it, does that look accurate to you?
A. Yes.
Q. Let me ask you briefly about your compensation, current compensation.
Do you have a salary?

A. Yes.
Q. And what is the base salary right now?
A. Roughly $315,000.
Q. And do you also get stock options or bonuses, stock as bonuses?
A. Occasionally, yes.
Q. And is there a cash type of bonus that you can get -- achieve?
A. Yes.
Q. And what is the basis for -- or criteria the company uses to provide you with stock or cash bonuses?
A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance.
Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus?
A. Generally, new submissions that are being made to the FDA. The number of first-to-file submissions that are made to FDA and posted on the FDA website in a particular

year. Approvals. Maintaining compliance with FDA regulations with respect to filing of annual reports. And as well as, you know, development of staff.

Q. And who conducts a review for you for this bonus?

A. My boss in the UK, Michael Banks.

Q. And is there generally a performance review that you receive, a written one?

A. Yes.

Q. And just last year, what was your bonus that you received, the last bonus you received?

A. Roughly the -- I guess the payout before taxes was roughly $137,000.

Q. And any stock?

A. Yes.

Q. And how much was that?

A. I honestly don't remember. Roughly -- I don't -- I'm not certain.

Q. Can you take a rough guess, please?

A. I believe somewhere in the range

of $100,000 of stock.

Q. And that would be of Teva Limited stock?

A. It is of Teva stock in the US, whatever stock is on the stock exchange in the US.

Q. That would be Teva Pharmaceutical Industries Limited?

A. I'm not certain of the legal entity.

Q. Do you know who your parent company is, of your employer?

A. I mean, I don't get into the legal entities. There's so many type of legal entities, so I'm honestly not certain.

Q. Do you interface with any regulatory personnel in Israel for the company?

A. Yes, occasionally.

Q. And who is that?

A. It would be -- Osnat is her first name.

Q. How do you spell that?

A. O-S-N-A-T. Cohen is her last name, C-O-H-E-N.

Q. And what's her position?

A. I believe she's a director in regulatory affairs.

Q. Is it for Israel or global or --

A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings.

Q. So what do you mean by a submission from Israel? A drug that they want approved in the US?

A. So any product that is being manufactured in Israel, if that product was going to be submitted to the FDA, her team would manage the documents and send them to my team here in the US.

Q. Is there anyone else in Israel you've interfaced with, you know, personally spoken with since you've arrived at the company that you can recall?

MS. HILLYER: Objection to form.

THE WITNESS: Sure, I do. I

mean, I'll list everybody's name who I worked in Israel with?

BY MR. CRAWFORD:

Q. Yes, please. That you've interfaced with.

A. Everybody that I spoke to in Israel.

Q. Right. Of any substance.

MS. HILLYER: Since 2013.

MR. CRAWFORD: Yeah.

BY MR. CRAWFORD:

Q. Maybe moving backwards, just who you can remember.

MS. HILLYER: In regulatory? Do you want to narrow it at all?

MR. CRAWFORD: Let's start with regulatory, yeah.

THE WITNESS: So Sigal Molgan is someone.

BY MR. CRAWFORD:

Q. How do you spell their name?

A. S-I-G-A-L. I believe her last name is spelled M-O-L-G-A-N, but I'm not certain.

Q. What's her position?

A. She is just a part of the regulatory affairs team in Israel.
Q. And what were the discussions about that you recall?
A. Nothing of substance. It was about products. So I can't specifically recall what product we spoke about, but...
Q. Anyone else?
A. Sure. Who else? Daniella Gutman.
Q. And what's her position?
A. She is in charge of research and development in Israel.
Q. And Gutman, how do you spell that?
A. G-U-T-M-A-N, I believe.
Q. Do you recall the substance of those conversations?
A. Again, they would have been product related, about a product that they were working on for submission to the US.
Q. Anyone else come to mind in regulatory?
A. I'm having a hard time recalling

names, but there would have been several members of the regulatory affairs team there that would have supported submissions in some way.
Q. How about other departments in -- I don't mean just small chitchat, anyone that you've had, you know, kind of, you know, more than a passing conversation, that you interfaced with in Israel?
MS. HILLYER: Objection to form.
THE WITNESS: Yeah. I mean, I can't -- any conversations with anybody in Israel would have been related to product filings that were being prepared for the US.
BY MR. CRAWFORD:
Q. That helps. Thank you.
Okay. Prior to -- let me ask you this: So at Teva, do you have any responsibility for opioid products currently?
A. Can you clarify what you mean by responsibility?
Q. Well, let's go back to this question.
What -- can you generally

describe your duties at Teva?
A. Sure. So the regulatory affairs team is the main liaison between FDA and the company. So the regulatory affairs teams coordinate ANDA, my team in the generic space coordinates ANDA submissions to the FDA. So it collects documents from the manufacturing sites where a product is to be manufactured. It puts that information together into the ANDA format that FDA expects. It makes the submissions to the FDA and works with FDA. If FDA has any follow-up questions, the regulatory affairs team would receive that information from the FDA, it would coordinate a call with internal stakeholders who are responsible for that product and coordinate a response back to FDA.
So it's getting products approved. It's maintaining compliance of approved products in terms of filing annual reports each year. If there are any changes to an application, any document that's been previously submitted to FDA, the regulatory affairs team will coordinate the updates and make possibly supplemental submissions to the FDA for

those products. From a high level, that's what the regulatory affairs team does.
Q. So basically, as far as interfacing directly with the FDA on issues, it's primarily run through your department. Right?
MS. HILLYER: Objection to form.
THE WITNESS: So the regulatory affairs team manages the approval process for new ANDAs and then maintaining compliance in terms of submissions of annual reports and keeping those submissions up to date.
BY MR. CRAWFORD:
Q. How about communications with the FDA? If the FDA wants to talk about a drug or some issue, is it your department that generally interfaces directly with them, or --
A. It would depend.
Q. Okay.
A. It would depend. If it was related to an application we filed and a specific question about that application, it would be us. But it could also be the quality team. If it was related to a product complaint, it would go

through the quality group. If it was related to an adverse event, it would go through the pharmacovigilance group.

Q. But any written submission to the FDA generally runs through your department as far as maybe final looking at it or approval or signing it?

A. Not necessarily --

MS. HILLYER: Objection to form.

THE WITNESS: Sorry.

MS. HILLYER: That's okay.

THE WITNESS: Not necessarily. So, for example, for pharmacovigilance activities, the pharmacovigilance team would prepare all reports. And then before it goes to FDA, there is a regulatory operations group, which is not under my responsibility. And they simply take the content from the pharmacovigilance team and submit it to FDA via the FDA electronic gateway.

BY MR. CRAWFORD:

Q. Where is the regulatory operations group located?

A. There is a group located in Horsham, Pennsylvania. There is a group located in Parsippany. And then there's also some individuals in India as well.

Q. And then pharmacovigilance -- let me go back.

So regulatory operations, that's currently.

How about in the beginning when you arrived, where was regulatory operations run out of?

A. So I would say when I began at Teva in July of 2013, the regulatory -- so regulatory operations was transitioning away from the regulatory group and starting a shared services group, how they are set up now.

Q. And did that occur with the Actavis acquisition or prior?

A. No. That was prior to the Actavis.

Q. And then pharmacovigilance, where are those reports kind of managed or collected up?

MS. HILLYER: Objection to form.

THE WITNESS: Yeah, I'm not sure. Can you clarify your question?

BY MR. CRAWFORD:

Q. So there's a pharmacovigilance aspect to -- they have to collect -- your company has to collect the reports of adverse events. Right?

A. Correct.

Q. And report them to the FDA, potentially. Right?

A. Yes.

Q. And so what departments are involved in pharmacovigilance and where are they located?

MS. HILLYER: Objection to the extent it calls for speculation.

BY MR. CRAWFORD:

Q. Currently?

A. The pharmacovigilance team is responsible for those activities. There are pharmacovigilance personnel. They were in the Horsham site.

Actually they've recently moved to the Parsippany, New Jersey site.

But who else is involved from pharmacovigilance outside of those two sites, there are several, but I'm not certain where they are all based.

Q. Are any of them potentially overseas?

A. Yes.

Q. And do you know where?

A. I believe in Croatia and in Israel.

Q. What are their functions in Croatia and Israel, do you know?

MS. HILLYER: Objection, calls for speculation.

THE WITNESS: I'm not certain.

BY MR. CRAWFORD:

Q. So as far as preparing or putting together an application for a generic drug, an ANDA, is your department involved in preparing or drafting any sections or parts of that for the FDA?

A. So can you repeat your question? Sorry.

Q. Yeah. Just -- your company

prepares applications for generic drugs that are called ANDAs, abbreviated new drug applications. Correct?

A. Yes.

Q. And they're in writing, presumably, and submitted to the FDA. Correct?

A. Correct. Electronically.

Q. And there are written portions of it.

And I'm trying to find out if your department is involved in preparing the written portions of the ANDA?

A. Yes.

Q. Does your department draft it or review it or is it a multi-department function?

MS. HILLYER: Objection to form.

THE WITNESS: Yeah, it's a combination. So my team works with the R&D team, the research and development team that's working on that product. Certain sections will come in drafted from the R&D department. My team will edit those documents to make sure that the documents flow and are easy to read

and consistent from one part of the application to the next.

And then certain sections of the ANDA my team would draft.

BY MR. CRAWFORD:

Q. And then for -- once a drug is approved, a generic drug, the company is required at certain points to submit the annual reports. Right?

A. Yes.

Q. And who prepares those annual reports? What's the process for putting one together?

A. Current process?

Q. Yeah.

A. So current process is much of this activity has been moved overseas to India.

Q. And is it -- what company does it in India?

A. I'm not certain of the legal entity name.

Q. Is it a Teva-related company or is it a third-party company?

A. It's Teva.

Q. So that department or -- in India, they're putting together the annual reports from various departments that are needed to provide content for it. Right?

A. Yes.

Q. Okay. And then once that annual report is prepared, do they send a copy -- and it has to be submitted in the US, do they send a copy to your department?

A. Occasionally, yes. If they have any questions. But for anything that's straightforward and they don't have any questions, then it would just be sent to the regulatory operations team to be submitted to the FDA.

Q. Is there a person now in charge of annual reports being submitted to the FDA for US-approved generic drugs?

A. Yes.

Q. And who is that?

A. Jill Pastore.

Q. And she is in your location?

A. Yes.

Q. And does she oversee the people

in India or --

A. Yes.

Q. Okay. So who's the person in India that's responsible for that?

A. Her name is Ulka, U-L-K-A. I believe her last name is Chorge, C-H-O-R-G-E.

Q. And is she actually located in Mumbai?

A. Yes.

Q. And do you know what company she works for?

A. I'm not certain of the legal entity.

Q. So the annual reports she prepares, are those ultimately reviewed by Ms. Pastore or her team before they're submitted or can they be submitted direct?

A. So no, again, it wouldn't be Jill who would review them. If there were any questions specific to an annual report that the team in Mumbai was working on, they would go to the US regulatory person who was assigned that project for questions.

But they can be submitted

directly if there are no questions.
Q. And the generic drug labels, the package insert, is it your understanding that they generally have to be the same or substantively the same as the name-brand labels?
A. Yes.
Q. And if there's a change to the name-brand label, is it your understanding that your company needs to change the generic label to substantively match the name-brand drug label?
A. Yes.
Q. And is there a process right now to monitor those changes and to update the generic labels for submission to the FDA?
A. Yes.
Q. And can you explain that process now?
A. Yes. So the labeling team is a part of my responsibility. They're currently based in North Wales, Pennsylvania and Parsippany, New Jersey. But they monitor the FDA's website for any RLD updates to labels.
Q. RLD being reference listed drug?
A. Yes.

Q. And that's generally the name brand drug. Right?
A. Yes.
Q. But if it's withdrawn, it can be another generic that the FDA designates. Right?
A. That's correct.
Q. Go ahead.
A. So they'll monitor the FDA website for any products that we have approved and even pending which are under review at FDA, to ensure that the labeling is kept up to date. And they'll make the changes and revisions to our label. And then they would make a -- if it's an approved product, they would make a CBE supplement submission to the FDA. And if it's a pending product, they would prepare the label and work with the regulatory associate who's responsible for that product to coordinate the submission to the FDA for that pending product.
Q. Right. And by CBE, you mean changes being effected, meaning that you could do it automatically without FDA preapproval. Right?
A. That's correct.
Q. Generally is there a target

turnaround time between the RLD change and when you would like to have the Teva change to the generic label to the FDA?
A. It varies. So it's really dependent on the types of changes that are made for the RLD product. If it's safety or labeling changes, we try to do those more quickly in accordance with a procedure. But if it's administrative changes, then, you know, those would take a little bit longer and less priority.
Q. If it's safety, what -- is there a target time that you have for that?
A. To turn it around within 30 days.
Q. And is there a standard operating procedure or guideline, written one, the company has on that process?
A. I believe so, yes.
Q. Is there a standard operating procedure written guideline for preparing annual reports on those generic drugs?
A. There would be a work instruction, I believe.
Q. Is that what it's officially called in the company, a work instruction?

A. I believe so. I'm not certain if it's a standard operating procedure or a work instruction.
Q. But it is in writing?
A. Yes.
Q. Have you seen that before?
A. Yes.
Q. This process for updating the label when the RLD does, has that always been that way since you got there? And if not, what was it before?
A. I'm sorry, can you repeat your question?
Q. Yeah.
So there's a process for updating your label if there's a change by the brand or the RLD. And you just described it.
Has that process changed over the time since you've been there, and if so, how has it?
A. It may have. I'm not certain. When I first joined the company, labeling wasn't part of my team's responsibility. And it became part of my team's responsibility with the Actavis

acquisition. So I'm not certain if it's changed since that time or not.

Q. So that responsibility landed with your department in about 2016 or '17?

A. Roughly, yes.

Q. Because Actavis was acquired -- the generic Actavis company was acquired in 2016 by Teva. Right?

A. That's correct.

Q. And you're not sure what the process was before it arrived at your department?

A. No, I'm not certain.

Q. What about -- you're familiar with the term "REMS." Right?

A. Yes.

Q. What does that stand for?

A. Risk evaluation and mitigation strategies.

Q. Can you briefly describe what a REMS is?

A. Sure. So REMS are put in place to ensure that the benefits of the drug still outweigh the risk when used -- when they're prescribed by doctors, when they're used by

patients and dispensed by legal pharmacists.

Q. And the REMS process was a process that was codified back in 2007 by Congress. Right?

A. That's correct.

Q. And it gave the FDA authority to require a plan of some sort for -- for supporting the safety of the drugs on the market. Right?

A. To ensure that the benefits of the drug still outweigh the risks. And that the drugs that have been approved by FDA are still, you know, prescribed and used as directed and as according to the approved labeling by the FDA.

Q. And currently there are REMS in place for opioid products, at least some opioid products manufactured and distributed by Teva. Right?

A. There's REMS in place for several different kinds of products, but opioids being one, yes.

Q. Is part of the REMS process is for those opioids, if you know, deal with kind of educating doctors about the proper use and risks associated with those opioid products?

A. I'm not certain of the specifics of the opioid REMS. I mean, I haven't been closely involved in that process.

Q. Have you reviewed them before?

A. I have not reviewed it.

Q. What department is responsible for making sure Teva's obligations under those plans are --

A. So there's a REMS --

Q. Go ahead.

A. Sorry. So there is a REMS group. It's actually -- it was actually a part of the commercial organization until October of 2018, of which time it moved to my responsibility.

Q. So "commercial," you mean the marketing department?

A. That's correct. Sales and marketing.

Q. And why was it moved to your department in October of 2018?

A. Because I think it's pretty well known that a single shared REMS, which we're talking about here, has been -- become a -- kind of a roadblock to regulatory approvals within the

past several years. The coordination efforts between FDA and many of the manufacturers who are involved in these REMS has really impacted approval times. So in order to better align and ensure communications within the regulatory team and the REMS team, it was moved to regulatory affairs.

Q. And that's your department. Right?

A. That's correct.

Q. And explain to me how it was a roadblock to regulatory approval, the REMS.

A. Generally speaking --

MS. HILLYER: I'm sorry. Objection to form.

Go ahead.

THE WITNESS: Generally speaking, these REMS require coordination between the brand company and a generic, and sometimes several generic companies. And just negotiating that single shared REMS has taken, you know, months, very long, longer to -- which -- longer to occur and happen than a typical goal date which the

FDA assigns to an application. So if it's taking the REMS process an extremely long time, if a goal date when FDA plans to take an action on an application comes up, the FDA will issue a deficiency letter because the REMS is not yet approved.

BY MR. CRAWFORD:

Q. So it was the interfacing with the other manufacturers to get an acceptable REMS that you could submit to the FDA that was holding things up?

A. That's part of it. It's also coordination from FDA and within FDA of the REMS group at FDA and then the reviewing groups in the Office of Generic Drugs.

Q. So when you get approval of a generic drug that has to have a REMS, a risk evaluation and mitigation strategy, you have to submit with your approval package a version of it that -- if it's a class-wide REMS, that's -- that is consistent with the class-wide REMS. Right?

A. That's correct.

Q. But it's not something that the

FDA gives to you and says, follow this directly.

It's something that you prepare to submit that the FDA will approve and is acceptable to them. Right?

MS. HILLYER: Objection to form.

THE WITNESS: So it's something that a generic applicant would have to work with the reference listed drug holder and any other manufacturers.

BY MR. CRAWFORD:

Q. And so the delay was really when you submitted -- there is a deadline, right, from the time that the application for the generic drug is submitted that the FDA is to take some kind of action, either approving it or not approving it. Right?

A. That's correct.

Q. If one of the conditions of approval was having an acceptable REMS, and you didn't submit that, they would -- they would -- that deadline would come and they would just simply not approve it and say it was deficient because it didn't have a REMS.

Is that the concern?

A. Not necessarily that it wasn't submitted. It could be that it was submitted but FDA still hasn't had an opportunity to complete its review of it, or FDA may have further changes that it would like to it. So it could be a number of variables.

Q. Got it. Okay. Thank you.

So before the function was moved to regulatory in October 2018 and it was in the hands of the commercial department or marketing department, what was the process for assuring adherence to the REMS, do you know?

MS. HILLYER: Objection to form.

THE WITNESS: I'm not clear of your question.

BY MR. CRAWFORD:

Q. Okay. So what did that -- part of the department's function currently with regard to the REMS is to make sure that the company's compliant with the REMS provisions. Right?

MS. HILLYER: Objection to form.

THE WITNESS: So no. The REMS team's responsibility is to work with the

other manufacturers to have agreements in place establishing the single shared REMS. So it's working with not only the companies, it's working with vendors to ensure that all the elements of the REMS are in place.

BY MR. CRAWFORD:

Q. Okay. But the company either -- I mean, somehow the company has obligations, but they're coordinating with other companies to fulfill them. Right?

A. That's correct.

Q. And I'm just asking what was the process prior to coming to you within the commercial or marketing department to make sure Teva's obligations in coordination with the other manufacturers were being complied with?

MS. HILLYER: Objection to form.

THE WITNESS: So again, prior to it coming to my organization, I'm not entirely clear what the processes were. My team would just work with the REMS associate that was responsible for a product to make sure that we had the

proper documents in our application.
BY MR. CRAWFORD:
Q. So who was in charge with the commercial or marketing department over the REMS programs prior to coming to your department? Is there a person or individual who kind of was in charge?
A. So you're asking who the REMS team reported to, which person?
Q. Who was head of the REMS team back then?
A. It's the same person who's head of the REMS team now, his name is Kishore Durgen -- sorry, Kishore Gopu.
Q. How do you spell that?
A. G-O-P-U is his last name.
Q. Is he based in Mumbai?
A. No.
Q. Where is he?
A. He's in Parsippany.
Q. Does he work -- do you know who he works for?
A. He works for Teva. I'm not sure of the legal entity name.

Q. All right. And Kishore is K-I-S-H-O-R-E?
A. That's correct.
Q. So he's head of the REMS team for the opioid REMS?
A. He's head of the REMS team for all REMS.
Q. And how long has he been in that position, do you know?
A. I'm not certain how many years.
Q. At least since you've been there?
A. Yes.
Q. And who does he report to now?
A. He reports to me.
Q. And who did he report to prior to you?
A. Tim McFadden.
Q. And where is Mr. McFadden located?
A. Parsippany.
Q. And what is his position?
A. I'm not sure what his title is.
Q. But he's with the commercial or marketing department?

A. Yes.
Q. And so now you're really responsible at least ultimately for the REMS compliance. Right?
MS. HILLYER: Objection to form.
THE WITNESS: So not for REMS compliance. I'm responsible for ensuring that the components of the REMS and what's required to be submitted to the FDA has been submitted to the FDA. But maintaining compliance, again, these REMS programs are quite complicated, they're managed by third parties outside of Teva. So they're the ones who would track and do any of the, you know, compliance checks. But we would coordinate the data from those companies and then submit regular reports to FDA about that compliance.
BY MR. CRAWFORD:
Q. So your department is responsible for the regular -- any regular reporting requirements under REMS to the FDA?
A. So again, yes. We would collect

the data from these third-party vendors who manage the REMS components and we would -- and actually, they put together even the reports and send it to each of the companies participating in that REMS. And then my team would put a cover letter on it and make that submission to the FDA.
Q. And what are these companies? What --
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. Can you identify them?
A. I'm sorry, can you repeat your question?
Q. What are the third-party vendors who are doing this REMS function for you?
A. I mean, I believe UBC is one. McKesson is another.
Q. McKesson?
A. Yes.
Q. Okay.
A. But I'm not certain of any of the other names.
Q. So your department, if there's a regular reporting requirement under the REMS,

that comes through your department ultimately then and now?

A. So again, it wouldn't come from my department.

Q. Through.

A. My department -- right. My department would receive the reports from these vendors and make the submissions to the FDA.

Q. Have you ever been deposed in an opioid-related case?

A. I mean, I've been deposed on products that were of the subclass of opioids.

Q. And can you generally tell me what those cases were? I mean, who was the plaintiff and, you know, what were they about?

A. I mean, the plaintiff was a patient who allegedly took an opioid product and had an event.

Q. And where was that case based out of? Do you know what court or state?

A. I'm not certain.

Q. And when was that deposition?

A. Last week, actually.

Q. And where was that deposition?

A. It was in Philadelphia.

Q. At Golkow or where?

A. No. Traurig. I don't remember the firm name, actually.

Q. Was it the questioning attorney's firm?

A. I believe -- no, I believe it was a Teva firm.

Q. Do you remember the name of the lawyer who took the deposition?

A. No, I do not.

Q. Any other opioid cases or opioid-related cases that you were deposed in?

A. None that come to mind.

Q. Going back to Exhibit 1, which is your LinkedIn page, you write in the summary, "aggressively identifying opportunities," "proven record."

What is that? What opportunities are you referring to?

A. I think it's talking about regulatory strategy.

Q. What kind of strategies?

A. When to make a submission, what

should be included in the application, things like that.

Q. Okay. And then it says, "proven record of...driving profitable growth."

What do you do that drives profitable growth?

A. It's just trying to find efficiencies in the work that we're doing. It's utilizing, you know, teams such as a team in India to help with more administrative tasks in terms of data entry and things like that, lowering cost bases in the US.

Q. And going down, you worked -- prior to Teva, you joined -- you were with Ranbaxy. Right?

A. Yes.

Q. And Ranbaxy manufactures generic drugs, too?

A. Yes, they did.

Q. And your position was a vice president, regulatory affairs, North America. Correct?

A. Yes.

Q. And what was your

responsibilities in that position?

A. Similar to my current responsibilities now. Again, it was overseeing the regulatory -- US generics regulatory affairs team and the Canadian regulatory affairs team for submissions to the FDA and as well as maintaining compliance in terms of filing annual reports and post-approval change supplements to the FDA.

Q. And does Ranbaxy manufacture, sell or distribute any opioid products?

A. Ranbaxy's no longer in business. They were bought by Sun Pharmaceuticals. So I believe when I was there they had some opioid products, but I'm not certain if they still have them or not.

Q. What were those opioid products, if you recall?

A. I believe it was oxycodone as well. I'm not certain of any others.

Q. Did you have any responsibilities with regard to that product, either submitting for approval or regular filings?

A. Again, the team that I'm responsible for would have managed those filings

and submissions to the FDA.
Q. And when were they bought out by Sun?
A. I'd say roughly 2015.
Q. And you left in June of 2013. Why did you leave for Teva?
A. It was really a growth opportunity for my career.
Q. And were you recruited by Teva?
A. A headhunter had called me.
Q. Do you have any plans of leaving Teva right now?
A. No.
Q. And then it looks like you were senior director of regulatory at Ranbaxy from December of '09 to February 2011. Correct?
A. Yes.
Q. And before that, you were with McNeil Consumer Healthcare. Right?
A. Yes.
Q. Is that a J&J-related company?
A. Yes.
Q. And did you have -- did they, McNeil Consumer Healthcare, manufacture, market,

sell or distribute opioid products?
A. No. McNeil Consumer Healthcare is the over-the-counter division of Johnson & Johnson.
Q. And before that, you were with Ranbaxy again as director of regulatory. Correct?
A. Yes.
Q. Any responsibility during this period for opioid products?
A. I'm not certain when those submissions were done. It's possible.
Q. And your background, educational background, is you went to Temple. Is MS a master's of science, QA/RA?
A. Yes, that's correct.
Q. So you actually had a three-year stint in quality assurance/regulatory affairs as your educational background. Right?
A. So the program at Temple is a master's of science in quality and regulatory affairs.
Q. And then your bachelor's degree

was bio and chemistry. Correct?
A. Yes.
Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly -- well, let me -- let's do 306. We'll mark the next exhibit.

- - -

(Deposition Exhibit No. Teva-Tomsky-2, Teva Opioid Market Share Calculation: All Opioids, Bates stamped TEVA_MDL_A_00455086 through TEVA_MDL_A_00455094, was marked for identification.)

- - -

BY MR. CRAWFORD:
Q. So we've marked what is here TEVA_MDL_A_00455086, which is some charts. The first page, "Teva Opioid Market Share Calculation: All Opioids," and then it goes on to list opioid products on the following pages. Have you ever seen a chart like this before?
A. I believe this is probably one of

the documents that I saw yesterday.
Q. And are you able to -- have you ever seen one before yesterday?
A. No.
Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and have a list run for you of those products?
A. No.
Q. And then you see here a list of various products, some being brand products. Right? Actiq and Fentora are brand products of Teva. Right?
A. Yes.
Q. And then the rest would be generic products on this list. Correct?
MS. HILLYER: You want him to look through the list on what page?
BY MR. CRAWFORD:
Q. If you recall or if you want to take some time and look, you're welcome to.
MS. HILLYER: I'm just going to object to lack of foundation. He testified he has no foundation for this

document.
MR. CRAWFORD: Other than you saw it yesterday, so...
MS. HILLYER: But he's never seen it before.
MR. CRAWFORD: He did yesterday.
BY MR. CRAWFORD:
Q. You did yesterday. Right?
A. I believe so.
MS. HILLYER: That doesn't establish foundation.
THE WITNESS: Can you repeat your question, please?
BY MR. CRAWFORD:
Q. Just wondering if that's -- these are generic opioid products, other than Actiq and Fentora, listed on this page?
MS. HILLYER: On the first page?
MR. CRAWFORD: On all of the pages.
MS. HILLYER: Take your time and look through it.
THE WITNESS: I'm not sure if -- Fioricet looks like a brand product, too.

I'm not sure what that is.
BY MR. CRAWFORD:
Q. Well, I'll just focus on actually what are in the -- listed in the chart starting at page 3 of the document.
A. Page 3 appear to be generic names other than Actiq.
Q. Yeah. And Actiq, Fentora and you mentioned Fioricet, which is on page 5, that's -- those are brands. Right?
MS. HILLYER: Objection to form.
THE WITNESS: It appears so.
BY MR. CRAWFORD:
Q. And so for these generic drugs -- some are -- some actually came over from Actavis, right, when they were acquired by the company in 2016?
A. Again, I would assume so. I'm not certain. Again, yesterday was the first time I saw this document. I've never seen it before other than that.
Q. But your understanding is Teva had some of its own generic opioid products prior to Actavis' acquisition. Right?

A. I believe so, yes.
Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid products in its portfolio. Correct?
A. Yes.
Q. So those new products were basically -- came within the purview of your department to ensure that the proper submissions were made at some point. Right?
A. Yes.
Q. To the FDA?
A. Yes.
Q. And what I want to know is -- so there are ongoing submissions required for all your generic products to the FDA, annual reports and the like. Right?
A. Yes.
Q. And is there any -- how is that responsibility divided up within your regulatory department? Are certain individuals given kind of responsibility for making sure those submissions are made for individual drugs? Or is it one person or how does that work?

MS. HILLYER: Objection to form.
THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form.
BY MR. CRAWFORD:
Q. So if a generic is coming out -- a generic product is coming out of a certain manufacturing site, how is that responsibility allocated? Is one of the sites Salt Lake City? Is that a manufacturing site for the company?
A. Yes.
Q. So, for example, if a product is coming out of Salt Lake City, being manufactured there, how is the responsibility for submitting ongoing reports and information to the FDA, how is that allocated or assigned?
A. So I have a team in Salt Lake City that manufactures products that are developed there and -- that manages products that are developed there and manufactured there.
Q. And is there somebody in Salt Lake City responsible for putting together the reports and making sure they're submitted to the FDA?

A. Yes.
Q. And is this a person that is physically based in that location?
A. Yes.
Q. And is it somebody who's part of your regulatory department?
A. Yes.
Q. And who is that for Salt Lake City?
A. The person who reports to me in Salt Lake City, her name is Cherri Petrie, it's C-H-E-R-R-I.
Q. And then when she prepares or -- I don't want to say it that way, strike that.
Is she the one who signs the annual reports for the drugs out of that facility?
A. So no. Again, as we had covered earlier, many of the annual reports now are done by a team in Mumbai.
Q. Right.
A. So for annual reports, the team in Mumbai would work on those. If they had any question, they would go to Cherri or her team.

That's a team member that's been assigned that product.
Q. Does Teva have a manufacturing facility in Irvine, California?
A. Yes.
Q. Is there a regulatory team there as well?
A. Yes. There's two people there.
Q. Who are they?
A. Eric Sullivan and Joshua Childs.
Q. And do they do the same thing, same process you described for Salt Lake City?
A. Yes.
Q. And do they report to you?
A. So they report to a person on my team.
Q. And who is that?
A. Anil Sachdeva.
Q. How do you spell that?
A. Last name is S-A-C-H-D-E-V-A.
Q. And he's located in Horsham?
A. He's in Parsippany.
Q. Is there any plan to move the Horsham folks to Parsippany?

A. Yes.
Q. And when is that supposed to be completed?
A. August 2019.
Q. Is that where you're going to be located?
A. I'll be located in Parsippany.
Q. Any plans to move physically your residence?
A. No.
MS. HILLYER: We've been going about an hour.
MR. CRAWFORD: Take a little break if you want.
MS. HILLYER: Yeah.
THE VIDEOGRAPHER: Off the record, 10:28.
- - -
(A recess was taken from 10:28 a m. to 10:44 a m.)
- - -
THE VIDEOGRAPHER: We are back on the record at 10:44.
BY MR. CRAWFORD:

Q. Prior to the break, you were talking about personnel that were located in Salt Lake City and Irvine, regulatory personnel who were responsible for some aspect of the FDA reporting regarding products manufactured at those sites. Right?
A. Yes.
Q. And also too you talked prior to that about a manufacturing site in Israel that you interface with some people with. Right?
A. Yes.
Q. Was it the same type of function, where they were in charge of certain submissions that would be made to the FDA with regard to products manufactured at those sites?
A. Yes. They would help coordinate documents from those sites related to those products that were manufactured at those locations.
Q. And do you know where the locations are in Israel?
A. Kfar Sava, Israel, and Jerusalem.
Q. How do you spell Kfar Sava?
A. It's K-F-A-R, S-A-V-A.

Q. And are those -- do you know what company owns those sites?
A. I'm not sure of the legal entity.
Q. Have you ever heard of the name TAPI, T-A-P-I?
A. Yes.
Q. Is that one of the manufacturing sites?
A. No, that's an API division of Teva. It's -- T is Teva, API is active pharmaceutical ingredient. So it's called TAPI.
Q. And just for the jury here, what is an active pharmaceutical ingredient? What are they making?
A. So an active pharmaceutical ingredient is the drug substance. So it's the active ingredient in a product formulation.
Q. And so then -- and that's a Teva entity, TAPI. Right?
A. Yes.
Q. And then that ingredient is supplied to the other Teva manufacturing facilities that then formulate the actual product?

A. TAPI will sell API to many companies.
Q. Including Teva?
A. Yes.
MR. CRAWFORD: We'll mark the next document here.
- - -
(Deposition Exhibit No. Teva-Tomsky-3, Organization Charts, Bates stamped TEVA_MDL_A_03486562 through TEVA_MDL_A_03486593, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. So we've marked a series of org charts here.
Have you ever seen this document?
A. Yes.
Q. And when did you last see it?
A. I don't recall.
Q. And this is dated July 8, 2013.
That's about the time you arrived at the company. Right?
A. Yes.

Q. And does this look like, scanning, to you generally what the structure of the regulatory -- various regulatory affairs departments were at Teva at the time?
A. Yes.
Q. And the first page references James G. Ottinger, a senior vice president of regulatory affairs, and under him is Michael Banks, vice president, global generics and OTC.
Mr. Banks, you had testified, is your current direct boss. Right?
A. Yes.
Q. And then according to this chart he reported at this time to Mr. Ottinger. Right?
A. Yes.
Q. Where was Mr. Ottinger physically located?
A. In Frazer, Pennsylvania.
Q. And do you know who employed him, who his employer was?
A. I don't know the legal entity.
Q. And did you ever have a chance to interface with Mr. Ottinger?
A. Yes.

Q. And he's no longer with the company. Right?
A. That's correct.
Q. Who replaced him?
A. Michael Banks.
Q. And you still report directly to Michael Banks then?
A. Yes.
Q. Did anyone fill Michael Banks' position?
A. No.
Q. Mr. Banks is in the UK. Right?
A. Yes.
Q. Then below that, below Mr. Banks, you have Gary Buehler, vice president, global regulatory intelligence and policy.
Do you know Mr. Buehler?
A. Yes.
Q. Where he is located?
A. He's retired.
Q. All right. When did he retire, about?
A. Roughly 2015.
Q. Did anyone take over his

position?
A. Not within regulatory.
Q. How about another department?
A. His responsibilities were kind of split up. We went through a restructuring, so some of those activities are being done now by the legal team.
Q. And what is -- it says he was global regulatory intelligence and policy.
What did that position entail?
A. It's just collecting information, new regulations, new policies that regulators were looking at. He had a strong focus on the US because he was formerly the head of the Office of Generic Drugs.
Q. With the FDA. Right?
A. Yes.
Q. Do you know when he joined the company?
A. I do not.
Q. And then going back, just a few things.
Were you -- we talked about pharmacovigilance and how that -- how that was

run when you arrived and currently.
Do you know how the pharmacovigilance was run prior to your arrival?
A. Can you be more specific?
Q. Let's say prior to 2009 -- Teva acquired Cephalon in 2009. Correct?
MS. HILLYER: Objection to form, assumes facts not in evidence.
THE WITNESS: Yeah. I'm not certain of the date of that acquisition.
BY MR. CRAWFORD:
Q. How about prior to 2010, do you know how the pharmacovigilance was run?
A. No.
Q. How about the REMS approval process, say, prior to your arrival, how was that run?
A. I think we talked about earlier, I'm not certain how it was operated. It was part of the commercial team.
Q. I said approval. Okay. I said approval process.
I mean REMS, you know, compliance.

MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. Do you know how that was run prior to your arrival?
MS. HILLYER: Sorry.
Objection to form.
THE WITNESS: Again, no.
BY MR. CRAWFORD:
Q. How about, do you know anything about how reporting to the FDA was run, say, in submitting annual reports for your drugs and so on? Do you have any knowledge about that?
A. Can you be more specific, please?
Q. Well, what the process was. You described the process for submitting annual reports when you arrived.
Do you know, can you describe that process, what existed prior to your arrival and moving backwards from there?
A. Yeah. I mean, generally speaking, the regulatory affairs teams, whether it was in Horsham, Pennsylvania or if it was Woodcliff Lake, New Jersey at that time, they were responsible for coordinating the documents

from the manufacturing sites and preparing the annual reports, and then making the submissions to the FDA.
Q. How far back did that process occur?
A. I'm not certain.
Q. DEA compliance, is there a DEA compliance department at Teva?
A. Yes.
Q. Does regulatory have any role in DEA compliance?
A. No.
Q. How about suspicious order monitoring?
A. No.
Q. How about reporting to the FDA information about its suspicious monitoring program?
A. I just want to clarify --
MS. HILLYER: Hold on a second.
BY MR. CRAWFORD:
Q. Go ahead.
A. Sorry, I just want to clarify.
You want to know if regulatory

has any responsibility?
Q. Correct.
A. Yeah. Regulatory has no responsibility, so I'm not aware. For the suspicious monitoring or even --
Q. Is there any regulatory requirement for opioids to report information to the FDA about its suspicious order monitoring program or interactions with the DEA?
MS. HILLYER: Objection to form and to the extent it calls for speculation.
THE WITNESS: Yeah. I'm not familiar with the process. It's outside of the scope of regulatory.
BY MR. CRAWFORD:
Q. Right. But I'm just wondering, as far as your interactions with the FDA, say in annual reports or anything like that, are you required to report or do you report to the FDA any of your interactions with the DEA or suspicious order monitoring activities?
A. So none of that information is reported to the FDA in the drug product annual

reports that the regulatory affairs team does, but I'm sure Teva has proper processes in place to do that sort of thing.
Q. How do you know they have proper processes?
A. I mean, Teva takes compliance very seriously. So I mean...
Q. Do you have personal knowledge that they're complying with all the processes?
A. I mean, again, it's outside the scope of regulatory, so I'm not involved in those things.
Q. So you're just making an assumption?
MS. HILLYER: Objection to form.
THE WITNESS: No. I'm saying that Teva is a company that is strong on compliance. We all have to do compliance training. And so I don't see how the company wouldn't comply with those regulations or requirements either.
BY MR. CRAWFORD:
Q. Do you mean currently or in the past or both?

A. It's always been a core value of Teva, to maintain compliance.
Q. All right. Let's go back to Exhibit 2.
MS. HILLYER: 3?
MR. CRAWFORD: 3, I'm sorry. The next page.
BY MR. CRAWFORD:
Q. Let me ask you this: Is this structure on page 1, is there a reorganization of the regulatory structure after the Actavis acquisition, or is this -- looking through this chart, is this generally how it exists today?
A. No. There was a complete restructuring.
Q. So let's go to -- and when did that occur, the 2016-2017 time period?
A. Roughly, yes.
Q. So let's go to the next page. This is, again, 2013, Michael Banks. That was your direct boss at the time. And you're down there, Scott Tomsky, VP, US generic.
Do you see that?
A. Yes.

Q. Was there a brand VP for US at this time?
A. Yes.
Q. Who is that?
A. The previous page.
Q. All right.
A. Because if you go back, again, this is -- Michael Banks is vice president of global generics and OTC. So generics. He had nothing to do with brand.
So if you look under Jim Ottinger on the first page, Susan Franks is vice president of global branded products.
Q. Got it. She was the counterpart to Mr. Banks then?
A. Yes.
Q. And was there a counterpart to you in the branded area?
A. It was set up very differently. So it's a global group. And it was broken up by therapeutic area.
Q. And is Ms. Franks, is she in Parsippany or in the US?
A. She left Teva.

Q. At this time, was she in the US?
A. She was in the US.
Q. So looking at page 2, you've got -- your structure is -- there's one US person here, and that's you. Correct?
A. Yes.
Q. In this structure at this level. Right?
A. Yes.
Q. Okay. And then you've got Roussell, Braeuner, Baader, Monvoisin, Spilsbury, they are EU heads or directors or managers in this chart. Right?
A. Yes.
Q. And are they -- do they -- they also report to Mr. Banks. Correct?
A. They did at this time.
Q. At this time.
And then -- and then over on the left, there's Alenka Lasic-Gasparevic, senior director, global RA.
Would she be -- have been in charge of the non-EU, non-US areas?
A. Generally speaking, she led the

regulatory team that was located in Croatia.
Q. And who had responsibility for, say, the non-US or non-North America, non-Europe regulatory at this time?
A. If you look further down, it's Iris Meisner, international regulatory affairs.
Q. Got it. Okay.
And who had charge of Canada at this time?
A. There was another individual, Mathi Mathivanan. And I believe at that time -- actually, I'm not sure. I'm not certain if he was -- where he was reporting into.
I think was reporting -- no. He was. He was reporting into the Canadian business at that time.
Q. Is there -- who is in charge of Canada now at your level?
A. I am.
Q. All right. So you -- so that's dealing with Canadian regulatory authority submissions. Right?
A. Yes.
Q. And why are you in charge in

Canada?
A. As a part of the restructuring with Actavis, it may have even happened prior to Actavis, I was given responsibility for not only US generics but also Canadian generics.
Q. Are you in charge of any other countries?
A. No.
Q. Who reports to you, directly under you with regard to Canada?
A. Mathi Mathivanan.
Q. And he's in Canada?
A. Yes.
Q. What city?
A. Toronto.
Q. And briefly, who's the Canadian regulatory authority?
A. Health Canada.
Q. Go to the next page. That's Alenka.
Is that a female, Alenka?
A. Yes.
Q. Okay. Lasic-Gasparevic in Zagreb, senior director, global RA.

Does she have any -- do you interface with her or does she have any responsibility with regard to the US operations?
MS. HILLYER: Objection to form, compound.
BY MR. CRAWFORD:
Q. Is her department or anything like that?
A. Sorry, can you repeat the question?
Q. Just trying to find out, her department or she have any responsibilities with regard to the US regulatory operations?
A. Are you now or are you asking back in 2013?
Q. Back then.
A. So back then, she would have managed any regulatory team that was in Zagreb, Croatia. And if there was products that were developed there or manufactured there that were coming to the US, her team would have compiled documents and sent them to my team.
Q. Similar to Salt Lake City and Irvine and Israel?

A. A little similar, yes.
Q. Next. My Bates numbers are cut off here, so I'm going to try to direct you to the correct page on that.
Would like to go to page 8 with Iris --
MS. HILLYER: Just give a Bates?
MR. CRAWFORD: Yeah. My colleague can do that here.
MR. JENSEN: Bates ending in 569.
BY MR. CRAWFORD:
Q. Now, she was -- you had mentioned she was your counterpart for the rest of the world. Right?
MS. HILLYER: Objection to form.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. I think we can move on to page 9.
This is you right here, under regulatory affairs. And you have Phil Erickson below you and Pat Jaworski.
Is Mr. Erickson, is he still with the company?
A. No.

Q. When did he leave?
A. Roughly 2015.
Q. And do you know where he is now working?
A. I'm not certain.
Q. Where was he based?
A. He was based in Horsham, Pennsylvania.
Q. And he was legacy Teva. He was there when you arrived. Right?
A. Yes.
Q. And do you know how far back or how long he'd worked there?
A. I believe more than 20 years. Actually, it was more than 20 years.
Q. Do you know if he's retired?
A. I'm not certain.
Q. Do you know why he left?
A. His position with the reorganization was no longer needed.
Q. Now, Teva's cut jobs worldwide pretty significantly in the last couple years. Right?
A. Yes.

Q. And are those layoffs completed yet or are they still ongoing?
MS. HILLYER: Objection to form.
THE WITNESS: Most of them are completed.
BY MR. CRAWFORD:
Q. And that was about 14,000 employees worldwide?
A. Roughly.
Q. What was Mr. Erickson's role at this time? What were his duties? And if you go to the next page, I believe there's a tree underneath him.
A. Okay.
Q. So if you could describe his duties at this time.
A. So at this time, there was two regulatory affairs teams. There was one in Horsham, Pennsylvania for the US generics, and there was one in Woodcliff Lake, New Jersey for US generics. So Phil was managing the team that was in Horsham, Pennsylvania.
Q. And this is his team below here on this chart on page --

MR. JENSEN: Bates 571.
BY MR. CRAWFORD:
Q. -- 571?
A. Yes.
Q. And Jill Pastore is down there on the lower right. Is she -- she was a director.
Is that her current position?
A. Currently she is senior director.
Q. And what is her job now? What are her duties?
A. So she is senior director of commercial regulatory and regulatory affairs launch preparedness, it's called.
Q. And what does that involve?
A. So she oversees the team in Mumbai who prepares the annual reports. And her team also manages tracking of various things, approvals, generic drug user fee dates, submissions that go into the FDA. She also has responsibility for the labeling team and the artwork management team.
Q. And what does the labeling team do?
A. So this is what we discussed

earlier. They monitor the FDA's website, they prepare labeling to support the US generic products.

Q. And there's Siva Vaithiyalingam, who is a director under Mr. Erickson.

Where is she located at the time?

A. It's a he, actually. And he was located in Horsham, Pennsylvania.

Q. What was his function?

A. He was -- I believe at this time, he was -- he was overseeing all submissions that went to FDA. He's a former FDAer, so he was doing -- he was performing a quality review of the applications before they went in, trying to identify any questions that he had, since he was a former FDA reviewer.

Q. And then over on his level, Rob Vincent, senior director, what was his position or what did that entail?

A. At that time, he was overseeing, you know, many of the products that were being managed by the team in Horsham.

Q. What does that mean, managed by the team? Just approvals, ongoing compliance or

reporting?

A. So the way the team was set up is a subset of applications that -- more or less the legacy Teva applications were managed through this team here. And he oversaw this team.

Q. Did that include opioid products?

A. It would include all products. It's possible -- yes. So Teva -- the legacy Teva opioid products would have been a subset of this group.

Q. Okay. And going to the next page, Pat Jaworski, was Pat a male or female?

A. It's a woman.

Q. Woman.

What was her responsibility?

A. So she was responsible for the regulatory affairs team that was located in Woodcliff Lake, New Jersey that supported the US generics submissions. These are primarily the legacy Barr and Ivax applications.

Q. So that would mean she -- I mean, what would she do with regard to those legacy drugs? Just oversee the ongoing submissions to the FDA?

A. Yeah. Again, her team would have oversaw the regulatory affairs responsibility in terms of submissions of new applications as well as maintenance of the approved applications.

Q. And Barr and Ivax were two companies acquired by Teva back in the middish 2000s?

A. I'm not sure when they were acquired, but yes.

Q. Ms. Jaworski, is she still with the company?

A. She is not.

Q. Okay. How about Mr. Vincent?

A. I'm sorry?

Q. Mr. Vincent --

A. So you're going back to the previous page?

Q. Yeah.

Is he still with the company?

A. He is not.

Q. Let's go to -- and I'm not quite sure the page.

MR. JENSEN: It's the first tabbed page, actually, with Terri

Booth-Genthe at the top.

MR. CRAWFORD: Yeah.

MS. HILLYER: Ending 582?

MR. JENSEN: Correct.

BY MR. CRAWFORD:

Q. Yeah. We'll go through these final tabbed pages.

Is Terri a male or a female?

A. She's a woman.

Q. Okay. And did we talk about her previously? I'm slipping memory on the names here.

A. No.

Q. What is global regulatory operations? What's that function?

A. So this is the team that primarily manages all the electronic submissions to the FDA.

Q. And how about other regulatory authorities for other countries?

A. Yes.

Q. And where is she located at this time?

A. At this time, she was located in

Frazer, Pennsylvania.
Q. Where is she right now, is she with the company?
A. She is not with Teva.
Q. Do you know who she's with right now?
A. I do not.
Q. Then go to the next page, we have Javier Monvoisin, head of regulatory information management.
At the time, where was Mr. Monvoisin located?
A. He was located in the UK.
Q. Did he or his department perform any functions with regard to the US generic drugs?
A. Yes.
Q. And what were those functions?
A. Again, it was submissions, electronic submissions to the FDA as well as other groups.
Q. So just coordinating getting the documents electronically submitted, or did they have any role in the substantive preparation of

what was submitted?
A. It was also managing databases and things like that.
Q. What kind of databases? Pharmacovigilance?
A. No. It was the regulatory affairs database.
Q. And what's in that database that you recall?
A. Global submission information, US filings, again, has to do with when the submission was submitted to FDA, any responses to the FDA, details about manufacturers, API suppliers, things like that.
Q. So if you wanted a report, you know, listing all the opioids and ANDA numbers from your generic opioids, would that be the person you would go to? Or that department back then?
A. No.
Q. Where would you go for that?
A. My team would manage separate spreadsheets for submissions for the FDA.
Q. And where would they get their

information from for that?
A. They would generate them themselves. It was basically kept in Excel. And it just tracked all submissions and submissions that were pending review with FDA, submissions that were approved, applications that were approved. It was too difficult to get information out of the global regulatory affairs database. So that was more for the global team to have, but it wasn't really for the US region to have.
Q. The next page, Karen Kulagowska, head of planning, metrics and reporting, what was her function back then?
A. So again, at this time, she collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what applications were approved.
Q. And where was she based?
A. In the UK.
Q. And is she still with the company?
A. Yes.

Q. Okay. Next is the next page, Jean Zwicker, is it a female?
A. I'm sorry?
Q. Is she female?
A. Yes.
Q. Jean Zwicker, senior director, GRA, that's global regulatory affairs. Correct?
A. Yes.
Q. Compliance and administration.
Did she or her department have any function or role with regard to the US operations for generics?
A. Yes.
Q. And what was her role in this department at this time?
A. It would audit to make sure that, for example, annual reports were being submitted to the FDA in accordance with the regulations, that labeling was being updated in accordance with the regulations to the FDA.
Q. Would there be -- was this an annual audit or periodic audit that would be performed?
A. I'm not certain how often they

occurred.
Q. Have you ever seen an audit report generated for your department from this department here?
A. Yes.
Q. And when was the last one you recall seeing?
A. Several years ago.
Q. And where was Ms. Zwicker located at this time?
A. Horsham, Pennsylvania.
Q. Horsham.
And did she do audits of regulatory affairs departments outside the US?
A. I'm not certain.
Q. Is she still with the company?
A. No.
Q. Next page is a senior director, global submissions management.
Who eventually -- it says vacant, but who eventually got this position, do you recall?
A. I'm not certain.
Q. Do you know what this department

does as far as anything that impacts the US?
A. Yes. This is the submission of the electronic documents to the FDA.
Q. And do you know where -- generally where these people are located on this chart?
A. If you look to the far left, Kevin Tompkins, he was located in Frazer, Pennsylvania. Ryan Hernandez was in Horsham. And you can see on here --
Q. Yeah. Frazer.
A. Yep.
Q. And Carrie Deming, North America, was she in US?
A. I'm not sure.
Q. It says Michael Aviv, associate director, Israel. Correct?
A. Yes.
Q. And where was the person these three reported to, Tompkins, Deming, Aviv, where was that person located?
A. I'm not certain.
Q. Next page is Jamie Warner, vice president of global labeling and brand

management.
Where was -- again, these are kind of unisex names, I apologize for having to ask this, but is Jamie --
A. A woman.
Q. A woman. Okay.
Is she -- where is she located at this time?
A. She was in Frazer, Pennsylvania.
Q. What was her role or function?
A. Global labeling and brand management.
Q. So that would be for not just US labels, but other Teva entities throughout the world. Right?
A. Yes.
Q. And was part of her function to make sure there was relatively uniform labels across -- and consistent labels globally?
A. Yes.
Q. For the Teva products. Right?
A. Yes.
Q. And did she have any obligations or role in keeping the generic labels up to date

with the brand or RLD labels in the US?
A. Yes.
Q. Was it her responsibility to -- I mean ultimate responsibility with regard to that function?
A. No. I mean, she wasn't actively doing that. She was overseeing the team.
Q. Right.
A. And Jane and Betty here were the ones who were primarily doing that.
Q. That's Jane Frahn, F-R-A-H-N, and Betty Shieh?
A. Yes.
Q. And they were just doing the US labels. Right?
A. Yes.
Q. And Ms. Warner, is she still with the company?
A. No.
Q. Do you know who has that role right now, kind of overseeing the people that do that?
A. There's not a global role right now.

Q. How about a US role?
A. Yes.
Q. Who is that again?
A. Charlene Salmorin.
Q. What's her last name? How do you spell it?
A. S-A-L-M-O-R-I-N.
Q. And then move on about three pages to Jane Frahn.
MR. JENSEN: It's Bates 590.
BY MR. CRAWFORD:
Q. Ms. Frahn is the woman who was in charge at the time of keeping the labels consistent with the brand or RLD. Right?
A. Yes.
Q. And she was based in Pennsylvania?
A. No.
Q. Where was she based?
A. She was based in Woodcliff Lake, New Jersey.
Q. Is she still with the company?
A. Yes.
Q. And does she still do the same

thing?
A. Yes.
Q. Then the next page is Betty Shieh, manager, generics labeling team.
She has the same function of keeping the labels consistent. Right?
A. Yes.
Q. That's all I have on that document.
Let's go to the next one.
- - -
(Deposition Exhibit No. Teva-Tomsky-4, Email dated 10/28/2015, Bates stamped TEVA_MDL_A_04344415, plus attachment, 50 pages, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. So we've marked TEVA_MDL_A_04344415.
It's an email from James Ottinger to Michael Banks, Mr. Tomsky here and others, dated October 28, 2015. "Subject: FINAL slide deck for RA work shop."

MS. HILLYER: Mark, does the leads -- do you know the Bates for the attachment?
MR. CRAWFORD: I imagine it followed directly from this email. It's probably the attachment there.
MS. HILLYER: I just want to make sure, because sometimes we've had issues with that.
MR. CRAWFORD: That's my understanding.
MS. HILLYER: Okay.
BY MR. CRAWFORD:
Q. So we've got a pretty substantial PowerPoint here. It goes up to 97 pages.
But I had some questions.
Was this the plan for integrating or restructuring regulatory affairs after or with the anticipated Actavis acquisition?
Let me strike that.
What was this? Is this familiar to you, this PowerPoint?
A. Yes.
Q. And can you tell me what this was

intended for?
A. I believe this -- actually, I know this was used for a meeting that Teva was having with Actavis leadership in the period -- time frame of October 2015, introducing the Actavis management in terms of how the Teva organization regulatory affairs team was set up.
Q. Did this have a -- or did this presentation or workshop -- it says workshop.
Is this an RA workshop? Is this kind of what it was?
MS. HILLYER: Objection to form.
THE WITNESS: Yeah. I mean, it was a meeting -- I guess we could call it a workshop since that's what it was called. But again, of the Teva regulatory affairs team and management from Actavis and their regulatory affairs team.
BY MR. CRAWFORD:
Q. Did this PowerPoint describe Teva's existing regulatory structure or any planned restructuring or both?
A. This discussed the existing

regulatory affairs team. It didn't discuss plans for restructuring of the team.

Q. All right. But after the acquisition, the departments, regulatory affairs departments were restructured. Right?

A. Yes.

Q. And is there -- I couldn't find a current org chart or how that's structured, but can you generally describe the changes that were made to the department with the restructuring?

A. There were quite a few changes made to the department, so I'm not certain what you would like to know.

Q. I understand. Yeah. Unfortunately, I could not find anything in the document production about the restructuring or what the current structure is.

So, you know, I apologize for asking such a broad question, but I'd just like to get your kind of -- what comes into mind as some of the basic, fundamental changes that were made to the department with the Actavis integration and acquisition?

MS. HILLYER: Objection to form.

THE WITNESS: Yeah, I mean, there was -- again, there was a lot of changes. There is new leadership, you know, from Actavis that was put in charge of the global R&D team. And then regulatory moved from reporting into someone who was legacy Teva to someone who was legacy Actavis.

And actually, there's been several reorganizations since even the close of the Actavis deal.

BY MR. CRAWFORD:

Q. And so who comes to mind that came over from Actavis that's in the current regulatory affairs leadership?

MS. HILLYER: Objection to form.

THE WITNESS: So when you say leadership, what do you mean?

BY MR. CRAWFORD:

Q. Kind of your position or above.

A. Currently at my position and above, I don't believe there's anybody from legacy Actavis in regulatory affairs.

Q. And I'm talking about, you know,

we just went through the 2013 chart and we had all this operations overseas and stuff like that.

Are there any Actavis people overseas that are heading up any of the types of departments that we looked at that you know of?

MS. HILLYER: Objection to form.

THE WITNESS: I'm not certain. We would need to look at the org charts and go by each one.

BY MR. CRAWFORD:

Q. How about in Pennsylvania and Parsippany, are there any Actavis people kind of in the level immediately below you that you can think of?

A. Yes.

MS. HILLYER: From legacy Actavis?

MR. CRAWFORD: Yeah.

THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. And who is that?

A. Joyce DelGaudio.

Q. And she is what position?

A. Senior director of regulatory

affairs.

Q. What is her function or role?

A. She manages a portfolio of products that have to do with the nonsterile, primarily solid oral dosage forms that are manufactured in various sites.

Q. And do these include opioid products?

A. Yes, I believe so. Some of them.

Q. And anyone else who comes to mind kind of in the positions immediately below you from Actavis?

A. Yes.

Q. Who else?

A. Janet Vaughn.

Q. What was her last name?

A. Vaughn.

Q. Janet Vaughn?

A. Yes.

Q. V-A-U-G-H-N?

A. Yes.

Q. And what is her role or function?

A. She manages the portfolio of products that are handled in the Florida

manufacturing areas.
Q. Is she based in Florida or up in --
A. Sorry?
Q. Where is she based?
A. She's based in Florida.
Q. Is she out of one of the manufacturing sites down there?
A. She's at the research and development site.
Q. And where's that?
A. Weston.
Q. Anyone else come to mind, Actavis, in a level below you?
A. Cherri Petrie.
Q. And what's her role or function?
A. We talked about her before. She manages the team in Salt Lake City.
Q. Yes.
Was Salt Lake City, was that a Teva site before the acquisition?
A. No. This particular site was a legacy Actavis site.
Q. Did Teva have its own site in

Salt Lake City?
A. They did. It was on the branded side, though.
Q. Right. And does that still exist, the branded?
A. I'm not certain. I don't deal with it.
Q. But the Salt Lake City site that reports to you that we talked about is a generic site that was an Actavis site before the acquisition?
A. Yes.
Q. And there were certain Actavis entities that are the ANDA holders for opioid products. Right?
A. I'm sorry, can you repeat your question?
Q. Well, when there's an abbreviated new drug application, there's generally a, what do you call it, an applicant. Right?
A. Yes.
Q. Or is there another word for it?
A. An applicant.
Q. And I'm just trying to find out

if there are any -- you know, what the entities are that you know of that were the -- that were the applicants for the Actavis side that came in for the opioid products?
A. I'm not certain who the applicants were for the opioid products. Again, Actavis used to file as Watson. They filed as Actavis Salt Lake City. Some of them were filed as Andrx, so I'm not certain.
Q. If you wanted to find out, you know, a list of opioid products that were Actavis products, how would you go about getting that list?
A. I would probably go to each of my direct reports and ask them for a list of opioid products that they were managing. All the opioid products are managed within the US, so they would come either from Florida or Salt Lake City, primarily.
Q. Is that where the opioid products are made, those two facilities?
A. Yeah. Primarily all the opioids are manufactured within the US, just because of DEA regulations.

Q. How about -- there are opioids distributed in Europe. Correct?
A. I'm not certain. I don't have responsibility for Europe.
Q. So the only two facilities that are manufacturing opioid products that are distributed in the US for a Teva-related entity are in Salt Lake City and Florida?
A. I'm not certain. There may be some in Elizabeth, New Jersey as well as Forest, Virginia.
Q. How about in Irvine?
A. No. Irvine is a sterile manufacturing facility. I'm not aware of any opioid products coming from that facility.
Q. Have you ever heard of a company called Teva Parenteral or Parenteral Medicines?
A. Yes.
Q. They're in Irvine. Right?
A. That's typically associated with the Irvine facility, yes.
Q. Getting back to Exhibit 4. Let's go to -- and the page numbers are in the upper right here, so this is describing here page 1.

It's got the agenda.

And the second bullet point is, "Generics RA Structure and Operating Principles." Michael Banks is global, you're listed for North America, and Jonathan Roussell is for European.

Does that mean that you guys were talking at this workshop or that's just identifying people in charge of the structures?

A. I'm not certain I understand your question.

Q. Did you present or talk at this workshop?

A. Yes.

Q. It is an agenda, so what was the agenda item on this page in relation to your listing on here?

A. Again, I'm not clear on your question.

Q. Okay. Was there an agenda for this workshop?

A. This appears to be the agenda.

Q. Right. And so what was your role in the agenda?

A. To present North America generics

RA.

Q. And so did Mr. Banks present on global?

A. Yes.

Q. And then shared services structure and operating principles, you've got regulatory operations, that's Ms. Booth-Genthe. And labeling and brand management, that's Ms. Warner.

Did they present at this as well?

A. Yes.

Q. And shared services structure, what does that mean?

A. So again, the way Teva was set up at this time is that there were shared services, so meaning these groups, regulatory operations and labeling brand management, would support -- would be a shared service for all the regulatory teams. So the North American team, the European generics team and the global regulatory affairs team.

Q. Go to slide 2. There seems to be kind of a circle of boxes around the central box called "Global Regulatory Affairs." The title

is, "Teva Regulatory Affairs -- Past State and Transformation (2011-2015)."

Can you just describe what this slide is trying to convey?

A. Yes. I mean, this was a slide that would have been presented by Jim Ottinger. So he's talking about how he created a global regulatory affairs team, which would have oversight, more or less, for all of these different groups.

Q. And where was global regular (sic) affairs at this time in 2015 based out of?

A. Frazer, Pennsylvania.

Q. And so again, slide 3 is Mr. Ottinger's slide. He says, "Given our journey of combining many RA groups into one, Teva transformed the RA function to the following overarching principles."

And he's talking about the, skipping down, the shared services and creating a global organization.

Was that something that Mr. Ottinger felt like he had done with the company?

MS. HILLYER: Objection, calls

for speculation.

THE WITNESS: I think it's clear on here what he's saying, too, is generics and brands are still very different and he's setting up focus areas. So they're separate business units that are under a common leadership, but they clearly function independently and separately.

BY MR. CRAWFORD:

Q. Brands and generics. Right?

A. Yes.

Q. And that's changed now; they're combined. Right?

MS. HILLYER: Objection to form.

THE WITNESS: No. So I would say still it's -- it's still the same. I mean, it's under one oversight and leadership, but there's dark lines between the two. I mean, we don't interact with the brand group at all.

BY MR. CRAWFORD:

Q. It does say, "create shared services."

So are there shared services between the two groups?

A. So again, yes. Those are the shared services that we've previously spoken about and those are the ones that do the submissions to the FDA. It's only the regulatory operations that it's a shared service. Labeling -- the global labeling brand management is no longer a shared service.

Q. Go to slide 4, second bullet point. It says, "Create centers of excellence for efficiencies and harmonization."

And then the third bullet point below that is, "Create a GM COE in Israel."

What does that mean?

A. I'm not certain.

Q. What does COE stand for, do you know?

A. I'm not certain.

Q. How about GM, global management?

A. I'm not certain. I don't know if it's global management or growth markets.

I believe, actually -- it's coming back to me. I think it's growth market

center of excellence in Israel.

Q. Do you know what that means, for what -- you know, what was --

A. I think it's stating that -- it's stating that the growth market regulatory operations would be managed in Israel.

Q. Growth market, what does that mean?

A. That means not US, not Europe. It's other countries.

Q. Developing type of countries?

A. Exactly.

Q. Page 8 kind of gives -- it says, "Today's focus." So it's got Mr. Ottinger at the top. It has global regulatory affairs. And then they're talking about global generics and OTC.

That's Mr. Banks, your boss. Right?

A. Yes.

Q. And global regulatory operations. I think we talked about that. And then global labeling and brand management. That's Ms. Warner. Global intelligence and compliance, Terri Stewart.

I think we talked about Terri Stewart.

Where is she located?

A. So we have not previously spoken about her.

Q. Okay. Is it she?

A. It's a she.

Q. And where is she located at this time?

A. She was in Washington, DC.

Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence?

A. No. So Mr. Buehler would have retired by now.

Q. I see.

Is Ms. Stewart still with the company?

A. No.

Q. Has she been replaced?

A. No.

Q. So what does it mean by regular shared services between these three operations? Is it shared between brands and generics, or is

it shared worldwide or both, or what does that mean?

MS. HILLYER: Objection to form.

THE WITNESS: It was shared between brand, generic and globally.

BY MR. CRAWFORD:

Q. And then the next page, 9, global regulatory affairs governance.

You've got senior VP global regulatory affairs.

Is that, at this time, Mr. Ottinger, right, as the top of the pyramid?

A. Yes.

Q. And then the executive leadership team, it says, "L3 heads of functional areas (5), plus HR and Finance Business Partners."

Were you one of the five heads they're referring to here?

A. No.

Q. Where do you fall on this pyramid?

A. Senior leadership team.

Q. Who were the five heads that you recall at this time?

A. If you go back to page 8, it's those five people that are under James Ottinger.
Q. Got it.
Susan Franks, global branded regulatory, where was she located?
A. Yes. We spoke about her before. She was in Frazer, Pennsylvania.
Q. Go to page 13. It does say leadership team there.
Are they talking about the senior leadership team in this chart here, from the chart on 9?
A. This is describing the global generic and OTC leadership team.
Q. And are you part of this team?
A. Yes.
Q. And you're North American generics here. Right?
A. Yes.
Q. Go to number -- page 21.
Can you describe what this chart -- if you -- did you make any presentation off of these slides? Were any of these your slides, if you know?

A. My slides begin on slide 28.
Q. And go till when?
A. And go to 42.
Q. Okay. Slide 21, can you -- I don't understand this slide. It says, from multiple sites, then an arrow to main centers, and then it has a bunch of -- you know, looks like factories there or something. And then two office buildings.
Can you describe what this is trying to convey here?
A. I didn't prepare this slide.
If you look at it in conjunction with slide 20, it's talking about the growth market regulatory affairs team. It appears they were split up between many sites and they created two main centers.
Q. Are any of these sites on the left in the US?
A. I don't believe so.
Q. CA, is that California?
A. It could be Canada. I'm not certain, though.
Q. Go to page 27.

It's global GNX, is that generics?
A. Yes.
Q. And OTC summary.
OTC is over the counter. Correct?
A. Yes.
Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's."
What is HA?
A. Health authorities.
Q. All right. So what -- is this a function -- one of the functions of one of the regulatory department divisions?
A. I'm not certain. This was a slide presented by Michael Banks, so I'm not certain what he was discussing here.

Q. Could it have been the regulatory intelligence function maybe?
MS. HILLYER: Objection.
BY MR. CRAWFORD:
Q. Within the regulatory department?
MS. HILLYER: Objection, lack of foundation, calls for speculation.
THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this.
BY MR. CRAWFORD:
Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA.
Is that Mr. Ottinger again?
A. No.
Q. Who was in that position?
A. This is me.
Q. That's you. Okay.
So these -- down below is Irvine.
That's one of your manufacturing facilities. Right?
A. Yes.

Q. And how does this Irvine facility relate to you in this chart?
A. Because if you see the steriles products?
Q. Yeah.
A. So those are the sites that support the sterile portfolio of products. Irvine is one of those sites. That's what I had mentioned earlier as well.
Q. Okay. And Haarlem, Zagreb and Godollo.
Haarlem is in The Netherlands. Right?
A. Yes.
Q. Zagreb in Croatia.
Where is Godollo?
A. Godollo is in Bucharest.
Q. In where?
A. Bucharest.
Q. Bucharest, okay. Romania.
So these are manufacturing sites that -- where they had regulatory people that -- that made submissions to you or -- sorry.
It's what you described about

having regulatory function in those sites for drugs that were sold in the US?
A. So not necessarily.
Q. Right.
A. So what this means is that there are products that are coming from these sites to the US. There may or may not be regulatory people at those sites. But if there's not regulatory people at those sites, then there's regulatory people at this time either in Horsham -- actually, only in Horsham, Pennsylvania, that would work with other functions to get the documents for those submissions.
Q. Got it.
Page 30, "Regulatory Affairs -- North American Generics." It says, under the second bullet point, "Compliance was suffering under previous models," including "Untimely submission of Annual Reports due to conflicting priorities for pre and post."
Were you aware of any untimely submissions of annual reports that was occurring under Teva's previous model?

A. Yes. So there was an issue with filing annual reports on time. That's what this is discussing. So for FDA, the regulations require you submit annual reports within 60 days. And the team was having trouble meeting the compliance to submit those annual reports within 60 days because the teams were not split for pre-approval and post-approval. So they were trying to manage all the pre-approval and post-approval activities on the teams. And with priorities, you know, and the thing that suffered was filing the annual reports on time.
Q. And that's 60 days from the anniversary date?
A. Yes. 60 days from the anniversary date of the approval.
Q. And what is the bullet point, "FDA enforcement and 483 observations within industry"? What was going on there with compliance suffering under the previous model?
A. So I was saying that I was aware of other companies receiving 483 observations from FDA during inspections for not filing annual reports on time. So that's why I was saying it

was becoming a focus area for FDA and a focus area for us to ensure that we maintain compliance.
Q. And was the FDA, was there ever any kind of warning or enforcement or 483 observations with regard to Teva in particular and its submission of annual reports?
A. Not that I'm aware.
Q. And wouldn't you feel this untimely submission was corrected, this issue? Or was it corrected?
A. It was corrected. It was corrected in 2014 time frame.
Q. And how was that corrected, by combining the pre and post?
A. So by separating actually the pre and post, and having a dedicated post-approval team that focused on submission of annual reports.
Q. And again, who is in charge of the post-submission function?
A. At that time?
Q. Just when you reorganized and put somebody in charge.

A. It was several people. At one point -- I mean, it changed from two to three people.
Q. How about when it was in the untimely submission phase, who was in charge of that?
A. It was Robert Vincent. We covered him before on one of the org charts.
Q. Right. Thank you.
MR. CRAWFORD: All right. That's all I have on that.
MS. HILLYER: So we've been going about an hour. I was going to try to go till noon if that would be a good lunch breaking spot or --
MR. CRAWFORD: Yeah, I think --
MS. HILLYER: -- a quick document to start --
MR. CRAWFORD: Okay. Yeah. Let's try -- I've got two documents. It might be pretty quick and then we'll go into the next section.
MS. HILLYER: Is that okay for you?

THE WITNESS: Yes.
MR. CRAWFORD: That would be a good breaking point then.
Why don't we just mark the next two.
- - -
(Deposition Exhibit No. Teva-Tomsky-5, Email dated 7/27/2017, Bates stamped TEVA_MDL_A_09019329 through TEVA_MDL_A_09019333 and TEVA_MDL_A_09019546 through TEVA_MDL_A_09019551, and Deposition Exhibit No. Teva-Tomsky-6, Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use, Bates stamped TEVA_MDL_A_04342838 through TEVA_MDL_A_04342849, were marked for identification.)
- - -
BY MR. CRAWFORD:
Q. So we marked Exhibits 5 and 6.
Let's go to 5 first.
That would be -- it looks like an email from Penny Levin to a number of people,

including Mr. Tomsky here, dated July 27, 2017.
The subject is "Comments to the Docket FDA Hatch Waxman Amendments."
Ms. Levin writes, "Hello All, Below please find the presentations given by Andy, Gregg, and Scott. Also find attached are the materials that were presented at the meeting combined into one document."
I have put on here -- you'll notice some document skip. And just to avoid chopping down a million trees, I put on just the three presentations by Andy, Gregg and Scott on the back, just to be selective here, but the email is reproduced here in its entirety.
Do you recall these talking points or presentations?
A. Yes.
Q. And what was the presentation for?
A. So this was an FDA public hearing on advancing generic access and overcoming barriers to generic competition.
Q. And it looks like on the next page, there's a GlobalMeet invite web meeting.

Do you see that?
A. Yes.
Q. And are these -- do these take place on a pretty regular basis, these global meetings?
MS. HILLYER: Objection to form.
THE WITNESS: So it's not necessarily a global meeting. This is the conference call service that Teva utilizes to have conference calls. It's just called global meetings.
BY MR. CRAWFORD:
Q. Generally it's got listed here a bunch of dial-in numbers for all across the world, including the US and other countries.
Was the intention for kind of all the regulatory people on this call to dial in that can make the call? Or, I mean, what was the intention here?
A. No, no. So --
MS. HILLYER: Objection to form.
THE WITNESS: Sorry.
MS. HILLYER: Go ahead.
THE WITNESS: So no. I mean,

again, this is just the standard service that Teva uses for conference calls. It sends out all these numbers for every meeting, whether or not there's people in those countries that are calling into the call. But only the people who are invited can call in, will have the access numbers.

BY MR. CRAWFORD:

Q. I see.

So this was sent out just to the people on the July 19th 5:20 p m. email to participate in this. Right?

A. Right. Because you never know where any of these people are at any one time. They could be traveling in any one of these countries and need to dial in and access it. So that's why the numbers are circulated.

Q. I get it.

So let's go to a Mr. Gregg DeRosa's presentation?

What was Mr. DeRosa's position at this time?

A. Generally speaking, he's in

charge of bioequivalent studies.

Q. And where was he based?

A. He's currently based in Parsippany, New Jersey.

Q. How about at this time, where was he based? US?

A. US.

Q. Okay. And then he writes, kind of about a little over midway through that one sentence paragraph, "The other topic I want to highlight here today is the need for definitive criteria for the approval of generic AD opioids."

Is that abuse-deterrent opioids?

A. Yes.

Q. And did you have any involvement at all in anything with regard to abuse-deterrent opioids?

MS. HILLYER: Objection to form.

THE WITNESS: Can you clarify your question?

BY MR. CRAWFORD:

Q. Are you familiar with abuse-deterrent opioids and what they are?

A. Yes.

Q. And did Teva develop any abuse-deterrent opioids?

A. Yes.

Q. And did they get approval for any abuse-deterrent opioids?

A. I'm not certain. I'm on the generic side, I'm not certain.

Q. How about brand?

A. I believe so.

Q. And that's Vantrela?

A. Yes.

Q. And the company decided not to market Vantrela. Right?

A. Yes, that's my understanding.

Q. You don't know why they didn't market it?

A. I have no idea.

Q. But they got approval for it. Right?

A. That's my understanding.

Q. That was run through your department. Right?

A. That's not correct. That was managed on the specialty side, the branded side.

Q. Got it.

A. So I had no -- my team had no responsibility for that.

Q. All right. But here they're talking about generic abuse-deterrent opioids.

Was Teva developing generic abuse-deterrent opioids at this time?

A. I believe so, yes.

Q. And had they submitted an application for any abuse-deterrent opioids?

A. I believe so, yes.

Q. Have any been approved or were any approved at this time?

A. I'm not certain. Again, we -- actually, I haven't said this, but we have a huge portfolio of products. I mean, we have more than 1,300 approved applications, we have more than 250 pending applications. So I'm not certain in this time period -- and even now, honestly, if -- what's approved and not approved, if it's an abuse-deterrent opioid.

Q. Were there any issues with having definitive criteria on getting abuse-deterrent opioids approved? And if so, what were the

issues?
A. Yeah, I think FDA continues to update its requirements and regulations. It publishes guidances on, you know, what is required to be submitted. But there's really a lack of clarity in terms of what the equivalent criteria are for these.
So I think that's what Gregg is discussing in his topic here.
Q. So it's like if there's a brand and they have an abuse-deterrent property, the question is, is what are the criteria for a generic trying to have a similar abuse deterrent property that would allow it to be approved.
Is that kind of the issue?
MS. HILLYER: Objection to form.
THE WITNESS: So FDA requires the generic to behave the same as the brand, but it's not certain in terms of, well, how similar is similar enough. So I think that's what Gregg was talking to in his discussion.
BY MR. CRAWFORD:
Q. All right. And then the next

page, page 548 is your presentation. Correct?
A. Yes. It wasn't a presentation. It was just a talk.
Q. So is this something that you just read into the record when you were at the meeting?
A. Yes.
Q. And just briefly describe to me what GDUFA II is.
A. GDUFA stands for generic drug user fee amendments. And GDUFA II is the second five-year period of the generic drug user fee.
Q. And briefly describe what GDUFA is.
A. So GDUFA has to do with the FDA's collection of fees for applications that are submitted for running the generic regulatory process. So FDA receives appropriations from the government, but then those appropriations are supplemented by fees. And it's not only on the generic side, but the generic user fees are fairly new versus the specialty or branded user fees.
Q. So in exchange for the generics

paying these fees, part of the GDUFA, I don't know, guidelines or regulations are that FDA has certain performance goals as well to speed the process along; is that correct?
A. Right. The fees are to supplement appropriations. So FDA agreed to review applications within a certain time frame. And then they could either issue a deficiency or an approval, depending on the quality of the information in that filing.
Q. And when it was passed, it was a five-year timetable. And then GDUFA II means that they were trying to or did get it renewed for five years?
A. That's correct.
Q. And was it renewed?
A. Yes.
Q. Then the last one, presentation, is an Andy Boyer.
He talks on the second to last paragraph about "Take" the example -- "for example the requirement to provide paper labeling and inserts with our medicines. Modernizing the labeling regulations to allow for e-labeling

would reduce the cost of medicines and improve the speed and accuracy of information for patients. These paper labels are a waste of our time and resources. More often than not they are discarded by our customers and never reviewed in their paper form by their intended audience, physicians."
Is that an accurate statement, in your view?
A. I'm not certain.
Q. So when Teva ships a product, a generic product, it generally is shipped to where, a wholesale distributor or a pharmacy, do you know that end of it?
A. I'm not involved in that part of it, I'm not certain where it actually goes.
Q. Let's go to Exhibit 6, please.
MS. HILLYER: Do you just limit it? Because we're near -- we've been going an hour and a quarter.
MR. CRAWFORD: Very limited. Probably less than five minutes.
PHONE SPEAKER: Before we move on to Exhibit 6, could you just tell us the

Bates number for Exhibit 5?
MR. CRAWFORD: Okay. 5 was --
MS. HILLYER: Well, it's a compilation.
MR. CRAWFORD: -- TEVA_MDL_A_09019329. And then a portion of the attachment to that letter, starting at Bates number, same prefix but ending with 19546. And then moving to the end of that document.
PHONE SPEAKER: Thank you.
BY MR. CRAWFORD:
Q. If I can go briefly on this.
So here, this is a "Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use."
When you have an advertising or promotional piece even for generics, you're required, as a company, to submit that to the FDA. Correct?
A. Yes.
Q. And this is a convention graphic for a product hydromorphone HCI injection USP CII. Correct?

A. It appears so.
Q. And this is -- somebody signed this, Jamie Warner, it looks like, for you. Right?
A. Yeah. So Jamie is the person we covered earlier, who is in charge of brand labeling and management.
Q. Right. Have you signed any of these personally?
A. No.
Q. Why does she sign for you? Why doesn't she just sign for her?
A. I have the same question, honestly. I'm not sure, because I had no involvement in it whatsoever.
Q. So -- but this is the convention graphic attached to it here that was submitted with this. Right?
A. It appears to be.
Q. And then there's a label for the product as well. Right?
A. Yes.
Q. Okay. And on the back of the label, it says, kind of the second to last

paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral Medicines...Irvine, California."
Do you have any idea why Hospira is manufacturing this for Teva Parenteral?
A. I'm not certain.
Q. Did Teva Parenteral, was this -- were they the ANDA holder for this drug?
A. I'm not certain. I'd have to look at the ANDA.
Q. If you wanted to look at the ANDA, how would you go about doing that?
A. So they're stored on a shared drive within our network. And I would pull open the application, I would look on a 356H form, which lists the applicant.
Q. And if you wanted to look at the approval letter for a product, how would you go about finding that?
A. I would ask someone on my team to find it, either the person who is responsible for

that product -- primarily, that's who I would go to.
Q. So there are people on your team -- when you say primarily responsible, are these people in your location or are these people at the manufacturing site that --
A. It could be either/or.
Q. All right.
MR. CRAWFORD: That's all I have for this line of questioning, so we can take a break for lunch.
MS. HILLYER: Okay.
THE VIDEOGRAPHER: Going off the record at 12:04.
- - -
(A luncheon recess was taken from 12:04 p m. to 12:38 p m.)
- - -
(Deposition Exhibit No. Teva-Tomsky-7, Approval Package for: Application Number: 76-168, 171 pages, was marked for identification.)
- - -
THE VIDEOGRAPHER: We are back on

the record at 12:38.
BY MR. CRAWFORD:
Q. Okay. We marked the next exhibit, Exhibit 7, which is "Approval Package for: Application Number: 76-168, Generic Name: Oxycodone Hydrochloride Extended-release Tablets, 80 milligrams, Sponsor: TEVA Pharmaceuticals USA, Approval Date: March 23, 2004."
Now, this was an approval package. There's no Bates number. It's something that we pulled off the FDA website.
So that is where this comes from.
But if we could take a look here.
Moving to the approval letter, which is page 4, if you could go to that, it's dated March 23, 2004. That's a stamped date at the top. And it's a letter from Teva Pharmaceuticals -- or to Teva Pharmaceuticals, USA, attention Philip Erickson. And it's signed by Gary Buehler, director, Office of Generic Drugs.
So this, again, we talked about Mr. Erickson.
He was at the company in that org

chart in 2013. Right?
A. Yes.
Q. And then Mr. Buehler, who is at the FDA here, you had mentioned he moved from the FDA to Teva.
He was on that same org chart. Right? That org chart. Right?
A. Yes.
Q. So this is -- it says, "This is in reference to your abbreviated new drug application (ANDA) dated May 8, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxycodone Hydrochloride Extended-release Tablets, 80 milligrams."
Are you -- and you could maybe take a look at Exhibit 2.
Is this a product that Teva still sells or markets right now, or at least as of 2016, Teva's chart?
MS. HILLYER: Objection to the extent it calls for speculation and lack of foundation.
THE WITNESS: Yeah. Even if I

looked at Exhibit 2, I don't know if it's currently being manufactured or not. Again, Teva has a vast portfolio of products, over 1,000, close to 1,300 approved applications, so I'm not sure which ones are actively being marketed or not.
BY MR. CRAWFORD:
Q. All right. Well, go to page 8. And you'll agree with me there does appear --
MS. HILLYER: Of exhibit?
MR. CRAWFORD: Of Exhibit 2, I'm sorry.
MS. HILLYER: Give him a second.
BY MR. CRAWFORD:
Q. It's the chart of drugs. Page 8, the top two.
You agree with me that this chart says -- reflects, "Oxycodone Hydrochloride Extended-Release tablets (Generic OxyContin)."
The first two boxes state that. Correct?
A. Yes.
Q. And then this approval is for

ANDA 76-168, oxycodone hydrochloride extended release tablets, 80 milligram.
You would agree with me that the approval is at least for some type of generic OxyContin. Right?
A. The approval is for generic OxyContin, 80 milligrams.
Q. Right. And then do you know if it's one of these two referenced in this chart, the first one showing prescriptions starting in 2015 and then continuing into 2016, the second one just in 2016?
A. I have no idea.
Q. Okay. All right. Are you aware that Teva, prior to this date, that Teva had a generic OxyContin approved?
A. Prior to when?
Q. Prior to today.
A. Yes.
Q. And were you aware prior to reviewing the chart yesterday that Teva had a generic OxyContin product?
A. Approved?
Q. Yeah. Approved, yeah.

A. Yes.
Q. What is your understanding of when that product -- this shows an approval in 2004, Exhibit 7. Correct?
A. Yes.
Q. And then Exhibit 2 has -- is referencing the sales of prescriptions in -- just in 2015 and 2016 for those top two boxes. Right?
MS. HILLYER: Same objections.
BY MR. CRAWFORD:
Q. I'm looking at page 8.
A. Right. But I am looking at page 2 to understand what the chart is. It says "Script volume and share of Teva products relative to all opioids."
So again, I'm not certain. I didn't prepare these charts. I'm not -- I didn't see them before yesterday, so I don't know what these numbers are, other than script volume, I guess. I don't see where share is.
Q. Well, share would be in that -- in the charts on 1 and 2. It says, "Teva CII opioid share." And there's a percent.
A. Okay.

Q. And then volume is above that. Scripts. And I assume that that type of number is being carried over. Certainly it isn't market share. It looks to me like script volume but, you know, that's how I interpret it.
Do you interpret it that way?
A. I'm not certain.
Q. So do you have any recollection of the generic OxyContin and whether that was marketed prior to 2015?
A. Yeah, I mean, I am not certain. Again, we have over 1,300 approved products. And I don't get involved in the details of every product.
Q. I understand.
But I'm just wondering if you have any knowledge or recollection of what was happening with generic OxyContin and whether it was being marketed or couldn't be marketed or anything at all?
A. No, nothing that stands out in my memory.
Q. Sure. And that's all I want to get, is just your memory.

A. Yeah. I'm not certain.
Q. If you don't, that's perfectly okay.
A. Right.
Q. So moving on with the letter, have you ever seen this approval letter before?
A. This specific one, no, not that I recall.
Q. How about one for generic OxyContin, have you ever seen an approval letter for that?
A. Not that I recall.
Q. So it does say on the third paragraph, the application is approved.
And so once an application is approved -- I guess unless there's a court injunction or something like that, Teva is free to market the product. Right?
A. Yes.
Q. Have you ever heard of a court injunction or something preventing Teva from marketing an FDA-approved generic opioid?
A. An opioid specifically, I'm not certain.

Q. But at least a generic product, you've heard of a court stopping the marketing. Right?
A. Yes.
Q. Even though it's FDA approved. Right?
A. Yes.
Q. And that might be because there's some kind of patent dispute or a dispute about whether Teva could legally market it and not infringe on the rights of a brand or another manufacturer?
A. Yes.
Q. So going to page 3 of the letter, the second paragraph there, starting with, "TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 milligram, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that TEVA was the first ANDA applicant to submit a substantially complete ANDA for Oxycodone

Hydrochloride Extended-release Tablets, 80 milligram, containing paragraph IV certifications to each patent listed in the "Orange Book." This exclusivity will begin to run from the date TEVA begins commercial marketing of the drug product, or upon the decision of a court holding the patents which were the subjects of the paragraph IV certifications to be invalid or not infringed; whichever occurs first."

And then moving down, second paragraph, the second line, "The Agency expects that you will begin commercial marketing of this drug product in a prompt manner."

So can you explain what this 180-day generic drug exclusivity is that's been granted here?

A. Sure. So for generic applicants, if you are the first generic applicant to file an ANDA, and if FDA receives that application wherein you are challenging patents that are listed in the Orange Book, if you are able to obtain approval, then you can potentially have a period of 180-day generic exclusivity where you, as an ANDA applicant and the brand, and typically

the brand would also sell an authorized generic, but you could be on the market for a period of six months before any other generic applicants can get approved.

Q. And that's a competitive advantage in the generic world, to have the 180-day exclusivity. Right?

MS. HILLYER: Objection to form.

THE WITNESS: 180-day exclusivity is very important in the generics.

BY MR. CRAWFORD:

Q. And why is that?

A. Because it's an opportunity to be on the market without any other generic competition, other than possibly an authorized generic by the brand.

Q. An authorized generic meaning one that the brand is allowing another manufacturer to make it but as a generic. Right?

A. Not necessarily. So it's -- an authorized generic is when the brand in essence packages its product and puts the label of another generic applicant on it.

So another generic company isn't

manufacturing it.

Q. Right.

A. The brand manufactures it and uses the label for another generic company.

Q. Okay. So the authorized generic is the company that it uses.

Is there a separate application process to be an authorized generic --

A. No.

Q. -- or can you just adopt the brand one?

A. It's all managed under the brand NDA.

Q. Do you know if Teva -- is Teva an authorized generic for any generic drugs that you know of?

A. Yes.

Q. So do you know if Teva is an authorized generic for any opioid products?

A. I'm not certain.

Q. So with this exclusivity, it does say, "The Agency expects you will begin commercial marketing of this drug product in a prompt manner."

That's because you would assume, wouldn't you, that that then triggers the 180-day period once you start marketing. Right?

MS. HILLYER: Objection to form.

THE WITNESS: Can you repeat your question, please?

BY MR. CRAWFORD:

Q. Yeah.

Is -- the FDA wants Teva to begin marketing the drug promptly.

Is that because, in your view and expertise in the area of regulatory affairs, that that's triggering the 180-day period. Right?

MS. HILLYER: Objection to form.

THE WITNESS: My understanding is that is because it would trigger the exclusivity period to start to run.

BY MR. CRAWFORD:

Q. Right. The goal of this is to incentivize drug companies to -- the exclusivity is to incentivize drug companies to challenge patents and get cheaper generics on the market, and in return the FDA or the regulations grant this exclusivity period for the successful

manufacturer. Correct?
A. So the goal of this is to bring safe, affordable, high quality, lower cost generics to the market and increase competition in the marketplace.
Q. By -- increase competition by bringing in a generic product where previously there has only been a brand?
A. Right. But only if they challenge patents and are able to bring the product to market before those patents expire.
Q. Right. Then after 180 days, presumably any company can issue a generic version of a drug after 180 days. Right?
A. Not any company. You would have to submit an application to the FDA and FDA would have to find it, you know, approvable.
Q. Right. Approvable meaning it's bioequivalent. Right?
A. Correct.
Q. And the same label, too?
A. But it's not only bioequivalent, but yes. It has to have the same label. It has to be -- you have to show that you can

successfully manufacture the product and have the proper controls in place.
Q. Right. But any manufacturer can make that attempt at that point in time to get approval, right, after the 180 days is up?
A. Yes.
Q. So then moving to the top of the last page. It says, "Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of the drug."
So in your view, is Teva, when it gets an ANDA approval by the FDA, that it must adhere to the reporting requirements of Sections 314.80 to 81 and 314.98?
MS. HILLYER: Objection to form.
THE WITNESS: Yes. So yes. I'm not certain what is specifically stated in these sections of the CFR without looking at them, but yes, this is what I spoke to earlier about ensuring compliance and filing annual reports, as well as the pharmacovigilance team filing

adverse event reports and what have you.
BY MR. CRAWFORD:
Q. Right. And that's what 80 and 81 do, one is dealing with pharmacovigilance reporting and the other is annual reporting. Right?
A. I'm not certain.
MS. HILLYER: Objection to form.
THE WITNESS: I'm sorry.
BY MR. CRAWFORD:
Q. I've got them here. Let's mark them and just confirm them.
- - -
(Deposition Exhibit No. Teva-Tomsky-8, Code of Federal Regulations Title 21, Section 314.80, 6 pages; Deposition Exhibit No. Teva-Tomsky-9, Code of Federal Regulations Title 21, Section 314.81, 8 pages; and Deposition Exhibit No. Teva-Tomsky-10, Code of Federal Regulations Title 21, Section 314.98, 4 pages, were marked for identification.)
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BY MR. CRAWFORD:
Q. So while we're marking this, we've marked Exhibit 8, 9 and 10, which are the three sections mentioned. And Section 8 is 314.80. Exhibit 9 is 3. -- 314.81.
These are kind of dense, but, I mean, you're head of regulatory, you're familiar with these provisions generally. Right?
A. Yes.
Q. And 314.80, correct me if I'm wrong, concerns -- you'll agree with me, it concerns reporting adverse events, say 15-day reports, and then quarterly and eventually annual reports on adverse events. Right?
MS. HILLYER: Hold on one second. I have -- my 8 and 10 are the same.
Are yours different?
THE WITNESS: No, they're different.
MS. HILLYER: So my 8 is section 80.
MR. CRAWFORD: Right. That's correct.

MS. HILLYER: 9 is 81.
MR. CRAWFORD: That's correct.
MS. HILLYER: I must have -- I just have a duplicate.
THE WITNESS: You don't have a 10.
MS. HILLYER: I don't have a 10.
MR. CRAWFORD: Do you have 10?
MS. HILLYER: No.
THE WITNESS: No.
MR. JENSEN: So you're missing 98?
MS. HILLYER: Yes.
MR. CRAWFORD: We'll throw it up on the board and blow it up. And you can have my copy.
MS. HILLYER: This is yours?
MR. CRAWFORD: Yes.
BY MR. CRAWFORD:
Q. So Exhibit 8, 314.80, dealing with periodic reporting and 15-day reports of adverse events. Correct?
MS. HILLYER: Is it just a two-pager?

You tell me, but I think you have two copies right there.
MR. CRAWFORD: Oh. That would explain it.
THE WITNESS: I have two copies, too.
MS. HILLYER: The actual exhibit is two copies, too, so do you want -- just for the record.
MR. CRAWFORD: Okay.
MS. HILLYER: Thank you. You gave me yours.
Do you care?
MR. CRAWFORD: No, I don't.
BY MR. CRAWFORD:
Q. So -- and then 314.81 is a different type of report that has to be submitted.
That's the annual report. Right?
A. 314.81 talks about NDA field alert reports, as well as annual reports.
Q. All right. So down at the bottom of the first page, annual reports, so it's your understanding that that's separate from the

reports that are submitted with regard to 314.80. Right?
A. Yes.
Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81?
A. Yes.
Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10.
A. Yes.
Q. All right. So let's look at Exhibit 9, which is the annual reports.
And this is applicable to both generic and brand manufacturers, this section. Right?
A. Which section?
Q. 314.81.
A. But which section?
Q. Well, the entire section.
Both brands and generics have to comply with the provisions of 314.81. Right?

A. So I can tell you, not necessarily.
So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report.
Q. All right. So that's starting on page 3, about three paragraphs down. Right?
A. Yes.
Q. So that's something that is not generally submitted within a generic annual report. Right?
A. Correct. And even -- yes, yep. Those two, (v) and (vi).
Q. But above that, are there any -- the provisions above that are applicable to generics and brands. Right?
A. Distribution data, summary, labeling. Distribution talks about authorized generics, so I guess there could be a case where a generic is allowing another manufacturer to distribute a generic under their label.
Q. Good point.
A. I think it's very rare, but...

Q. Okay. So you're saying (ii)(b) might not apply to all generics. It certainly doesn't apply to a brand. It's just a section applicable to an authorized generic. Right?

A. Well, it would -- it would apply to a brand.

Q. Okay.

A. And I guess some generics may choose to distribute or allow another company to distribute under their ANDA. I'm sure it happens.

Q. So when you have -- when you have an authorized generic, do you have to have an ANDA number for the authorized generic drug that you distribute, or do you just go under the NDA number of the brand?

A. So if you have an authorized generic that's being distributed under an NDA, it would all be associated with that NDA number. But I'm saying I can foresee an example of when an ANDA applicant also may choose, for some other reason, to allow another manufacturer to distribute under the ANDA an authorized generic.

Q. So I'm trying to understand.

Is there -- they might have an ANDA for the same drug, just simply be an authorized generic because the brand is making it for that generic company?

A. I'm not sure I understand what you just said.

Q. All right. I'm just -- you were talking about another generic manufacturer under an ANDA that's for an authorized generic. I didn't understand that.

A. So we spoke about an authorized generic as it relates to an NDA, how they would maybe supply the product to a generic company and a generic company would give the brand company its label to put on the NDA product. So it would be sold as an authorized generic. Correct?

Q. Right.

A. So then there's another case that I can foresee where an ANDA holder --

Q. Of what?

A. I'm sorry?

Q. An ANDA holder of what?

A. Of any product.

Q. Okay.

A. Say -- I don't know, say ibuprofen, for example. Say I, Scott Tomsky, have an ANDA for ibuprofen. I may choose to say, hey, here you go. If you want to put your label and distribute product under my ANDA, so that could technically be an authorized generic as well.

Q. So a generic authorizing another generic company to make its product under its ANDA?

A. So again, that other company wouldn't make the product, it would just simply put its label on the product that's being made under the ANDA.

Q. Got it.

Okay. Going back to 314.81, "Applicability."

It says, "Each applicant shall make the reports for each of its approved applications and abbreviated applications required under this section and Section 505(k) of the act."

(b) is "Reporting requirements. The applicant shall submit to the Food and Drug

Administration at the specified time two copies of the following reports."

And skipping down to the bottom of page 1 to 2, "Annual report." It says, "The applicant shall submit each year within 60 days of the anniversary date of U.S. approval" -- again, that was the 60 days you referenced earlier. Right?

A. That's correct.

Q. -- "of the application, two copies of the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2252 (Transmittal of Periodic Reports for Drugs for Human Use), and must include all the" relevant "information" -- "all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval that ends on the U.S. anniversary date. The report is required to contain in the order listed," colon.

So the first item is "Summary." And it's required to provide "A brief summary of significant new information from the previous

year that might affect the safety, effectiveness, or labeling of the drug product. The report is" require -- "also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information."

So are your annual reports as, again, a business practice, do they contain this summary that's just described in subdivision (i)?

A. So an ANDA annual report will contain a summary of new information related to: If there was any changes to the approved specification, if there was changes to any of the manufacturing batch records, if there was a supplement that was filed maybe to add another API source that we talked about. Anything like that.

So it would contain a summary, but not necessary a summary of safety information, which is stated here.

Q. Why wouldn't it contain that?

A. Because ANDAs aren't required to generate safety or efficacy data. That's only a requirement of NDAs.

Q. What if the ANDA holder becomes aware that its generic drugs are being abused or misused, say in the case of an opioid, during that one-year period, and that maybe the label isn't -- and the doctors aren't properly prescribing the drug.

Is that something that you feel Teva would be required to put into its annual report?

MS. HILLYER: Objection to form.

THE WITNESS: Can you break down your question for me, please?

BY MR. CRAWFORD:

Q. Okay. So let's say Teva became aware during that annual period that, say, its generic OxyContin was being misprescribed and abused and misused by patients to become addicted or -- would -- and they became aware of that information during that period.

Is that something that you feel that Teva would be required to report in its annual report?

MS. HILLYER: Objection to form.

THE WITNESS: So I can say from

an ANDA perspective, generic applicants primarily in their annual reports provide a summary of the chemistry, manufacturing and control changes, which is what I described earlier, any changes that are made during the reporting period as it relates to anything that's already approved in the application.

The scenario that you described I would think would be something that would be included in the other type of reporting that we looked at in 314.80, possibly. But it's nothing that would be submitted in a drug product annual report like this for an ANDA.

BY MR. CRAWFORD:

Q. But wouldn't knowledge about abuse of its drug and misuse be information that might affect the safety of the generic product?

A. Again, I'm not certain. Again, what I'm saying is, in my years of doing regulatory affairs and ANDAs, the information that's required to be submitted in an ANDA annual report pertains to the summary of the chemistry

and manufacturing changes for a product.

Q. But isn't the purpose of this section to alert the FDA that there's a problem with the safety of the drug or how it's being prescribed so they could potentially or with the manufacturer take corrective action?

MS. HILLYER: Objection to form.

THE WITNESS: No, that has not been my experience.

BY MR. CRAWFORD:

Q. And it does say that the report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information.

So wouldn't you agree with me that if, say, for the generic OxyContin, if that was marketed prior to a REMS approval, and the company became aware that a drug was being misused or abused or misprescribed, say in the case of an opioid drug, wouldn't, one, Teva be required to report that in an annual report and also report corrective steps it was taking?

MS. HILLYER: Objection to form.

THE WITNESS: So no, again, what

I'm saying is that in my experience, in my communications with FDA, is the expectation that an ANDA applicant in its annual report file changes related to the chemistry and manufacturing controls. And what that previous section was talking about what would be what's covered in Section 314.81(b)(1), which talks about NDA field alerts, ANDA field alert.

So if you receive a product complaint with respect to maybe a product not working or somebody didn't have enough tablets in their bottle or maybe the wrong imprint code was found in a bottle, that's when it would trigger an NDA field alert to be filed, and those are the types of summary and information that would be included in this annual report.

BY MR. CRAWFORD:

Q. And what section is that here? Can you point that out? You've mentioned it, but it's --

A. I'm sorry, it's 314.81(B)(1), NDA field alert.

Q. And so what page is this on?

A. It's on the first page.

Q. So basically the field alert report would be information concerning any incident that causes the drug or its labeling to be mistaken for or applied to another article.

So that's like a mistaken use of the drug, they think it's some other drug or something?

A. So -- correct. It could be that somehow the wrong label was put on the product or there was an error in the label that was on the product. So those are the type of events that would have to be reported to FDA in a field letter and then summarized again in the annual report.

Q. And then the second thing is, "Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product

to meet the specification established for it in the application."

So that's concerning really contamination or a defective batch of product. Right?

A. Right. So that's talking about if a patient receives a product and they look at it and it turned brown and it's supposed to be white. Or if the manufacturing company had -- it runs routine stability reports. So if it ran a report and it received a result that was outside of the approved specification. Those, again, are instances that would trigger a field alert and that type of information would be summarized in this section.

Q. Right. And that has to be done within three days. Right?

A. So the field alert needs to be filed within three days. But then the annual report would capture a summary of any field alerts that were filed within that one-year reporting period that the annual report is covering.

Q. Right. But that doesn't really

cover the situation I'm talking about, you'd agree, about Teva becoming knowledgeable that its drug is being abused or misused or misprescribed that's leading to addiction or some kind of safety issue like that. Right?

MS. HILLYER: Objection to form.

THE WITNESS: Again, the scenario you described is not covered in ANDA annual reports.

BY MR. CRAWFORD:

Q. But it does say, you agree with me, the summary is supposed to provide a summary of significant new information from the previous year that might affect the safety, effectiveness or labeling of the drug product. Right?

Are generic companies exempt from that in any way?

MS. HILLYER: Objection to form.

THE WITNESS: So what I'm saying -- so what I'm saying is yes, this section of the regulation is for both NDAs and ANDAs. And there are different responsibilities for NDA applicants versus ANDA applicants. And in my

experience in working with FDA and in the industry for over 20 years, there's never been a requirement in ANDA annual reports, and nor is it FDA's expectations that any safety or efficacy information is reported in an ANDA annual report. That is left to the NDA holder.

BY MR. CRAWFORD:

Q. What about a name brand drug, if they become aware of a safety issue with regard to abuse or misuse in the prior year, would they be expected, in your view as a regulatory person with regulatory experience, to report that in their annual report?

MS. HILLYER: Objection to form, calls for speculation, to the extent it's outside of his purview.

THE WITNESS: Yeah. Again, I am not certain. I've worked in the generic industry for 99 percent of my career.

BY MR. CRAWFORD:

Q. All right. So where -- is there a written guidance or -- from the FDA or anything in writing that you can point to that generic

manufacturers don't have to report the type of safety information example I gave to you on abuse and misuse?

A. I'm not aware of anything written. I know I've specifically had conversations with FDA about this when I was at Ranbaxy.

Q. Ranbaxy.

How about at Teva?

A. No.

Q. And who is the person at the FDA you had the conversation with?

A. His name was Peter Rickman.

Q. And what was his position?

A. He was a director in the Office of Generic Drugs.

Q. And is there anything in writing? Did he confirm this in email or did you confirm it in any kind of report with Ranbaxy?

A. Not that I recall.

Q. What was the context of when it was raised?

A. It was, again, confirming what information had to be filed in an annual report.

I don't know how it came up. There was some discussion that was going on within the company about what needed to be filed in an ANDA versus an NDA annual report. And, clearly, the clinical and safety information.

Q. But he said you don't have to report any safety information other than the clinical and safety information?

MS. HILLYER: Objection to form.

BY MR. CRAWFORD:

Q. I'm just trying to understand.

What did he tell you, you didn't have to report that or just simply told you that you had to report the clinical information?

A. He said that the safety and efficacy information is not applicable to an ANDA.

Q. Did he give a reason for that?

A. No. It's been a long-standing position from the agency.

Q. But it's never been put in writing, as far as you're aware?

A. Not that I'm aware of.

Q. Did you hear it from anyone else

at the FDA that you didn't have to put this information in an ANDA?

A. No. I spoke with him.

Q. Just Mr. Rickman?

A. Correct.

Q. How many occasions did he tell you this?

A. It was one conversation that I had with him.

Q. Okay. And was it -- was there a specific safety issue that you ran by him about whether you had to put it in or not?

A. No.

Q. It was just a general question?

A. Correct.

Q. All right. The next section, (ii)(a), "Distribution data," it says, "Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage units of each strength or potency distributed (e.g., 100,000 over

5 milligram tablets, 50,000 over 10 milliliter vials), and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required."

Is that something that Teva, through its normal business practices, includes in its annual reports for its ANDAs?

A. Yes. Distribution data.

Q. And who currently at Teva is responsible for collecting this information and putting it in the annual reports?

A. So the regulatory team would collect that from the supply chain and commercial marketing team.

Q. The regulatory team being the one putting the annual report together?

A. Yes. But it -- it's collected -- I believe it's collected in the US, and then that information is given to the team in India.

Q. And where in the US is it collected from? What department? I mean, from all the charts we went through, does that -- do you remember where that responsibility lies?

A. So I believe it's Jill Pastore would still collect that data and then save it on the shared drive and make it available to the team in India.

Q. And then these annual reports, if you wanted to get a copy of an annual report, can you personally go on the shared drive and pull it up, or how do you get them for a drug?

A. Yes, yes.

Q. Do you just look up the drug and there's a folder or a search pulls them up or something?

A. Yes. I would search by the name of a product or an ANDA number.

Q. I would love to have an example, but we have trouble finding them in the document production, so I don't have an example to show you, so we'll talk about it. Either I can't find them or they're not there, so --

MS. HILLYER: I think we offered to give you samples and told you to follow up with us on which ones you wanted samples of, and then you never did.

MR. CRAWFORD: Well, I definitely want them.

So, but let's --

MS. HILLYER: I think we're a little past that timeline.

MR. CRAWFORD: Got it.

MS. HILLYER: But we can talk about that offline.

MR. CRAWFORD: Understood.

BY MR. CRAWFORD:

Q. Okay. So the next section is "Authorized generic drugs." We kind of went through that. It says, "If applicable, the date each authorized generic drug (as defined in... 314.3) entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name."

So that's a section that you would fill out only if you were an authorized drug. Right?

A. Only if you were distributing an authorized generic under that application.

Q. Right. So -- so this -- so basically, I'm just trying to understand.

So if you were an authorized generic, if Teva was, and -- from some brand, my understanding of what an authorized generic is, is that brand is making the drug and it's being distributed by the generic under their name. Right?

A. Yes.

Q. Does that generic have to file an annual report for that?

A. No.

Q. That's filed by the brand?

A. Correct.

Q. And then this section would be filled out by the brand?

A. Correct.

Q. All right. And then third is, "Labeling. Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels."

That is also included in these annual reports as a practice. Right?

A. Yes.

Q. All right. That's all I have on

those, but let's go back to Exhibit 7, which is the approval package for the generic OxyContin.

Let's go to the label, which is a couple of pages afterwards, under "Final printed labeling."

So is this the label that was approved for Teva in this package for this generic OxyContin.

In your professional career of seeing these approvals, is this generally how it comes back to you?

A. Yes, it appears to be.

Q. And so this would be taking -- taking a look at the last page of the label, it says, "Manufactured by Teva Pharmaceuticals USA."

So this would be Teva's label dated June of '03. Right?

A. Yes.

Q. All right. And then again, to be a generic drug, you're -- this is called -- when it's approved, it's called the approved label. Right? Is that kind of a term of art, approved label?

A. Yes.

Q. And then there's other labeling, too. It's not necessarily a term of art, approved label.

It could be considered labeling, an advertisement or a "Dear Doctor" letter or something. Right?

MS. HILLYER: Objection to form.

THE WITNESS: It's possible.

BY MR. CRAWFORD:

Q. Do you refer to those as approved labels?

A. I'm not sure I understand your question.

Q. Do you refer to an advertisement as an approved label?

A. No. An advertisement would be based on the approved labeling.

Q. But it's still considered labeling, because it has information about the drug.

MS. HILLYER: Objection to form.

BY MR. CRAWFORD:

Q. Technically. Correct?

A. Generally speaking, it would be

accompanied by the approved label as well.

Q. Is a "Dear Doctor" letter, is that considered technically labeling?

MS. HILLYER: Objection to form.

THE WITNESS: I don't know. I mean "Dear Doctor" letters aren't used on the generic side, typically. It's only something that would be used on a branded side.

BY MR. CRAWFORD:

Q. Can a generic manufacturer send out a "Dear Doctor" letter about a drug, in your view?

MS. HILLYER: Objection. Objection to form, calls for a legal conclusion.

THE WITNESS: Yeah. I'm not certain. I don't think it's ever been done that I'm aware of.

BY MR. CRAWFORD:

Q. Do you know if there's any regulatory restriction precluding a generic drug manufacturer from sending out a "Dear Doctor" letter?

MS. HILLYER: Same objection.

THE WITNESS: I'm not certain.

BY MR. CRAWFORD:

Q. Can a generic drug company communicate information to doctors about its generic drugs consistent with its approved label?

MS. HILLYER: Objection to form.

THE WITNESS: Can you repeat your question again? Sorry.

BY MR. CRAWFORD:

Q. Can a generic drug company communicate information to doctors about its generic drugs consistent with its approved label?

A. I think so, but I don't know any generic companies that have a sales team for generics.

Q. Do they have safety teams, generic drug companies?

MS. HILLYER: Objection to form, calls for speculation.

THE WITNESS: Yeah. I'm not sure what you mean by that.

BY MR. CRAWFORD:

Q. Well, anyone in charge of safety,

if there's a safety issue or a danger that comes out, is there any kind of dedicated person designed or that's -- that exists within Teva, their generic side, to --

A. I think what you're describing is --

Q. -- address those issues?

A. Sorry. I think what you're describing is something that would be managed by the pharmacovigilance team.

Q. What if the company became aware that its drug, its generic opioid products were being abused or misused by doctors, and the doctors did not appear to understand the proper use of the drug or the safety risks with regard to abuse and addiction, is it your view under the regulations that Teva could send a "Dear Doctor" letter or other information consistent with the label to remind doctors how to properly use the drugs and about its risks?

MS. HILLYER: Objection to form.

THE WITNESS: Yeah. Again, I'm not certain, especially for this class of drugs, which already has a approved risk

evaluation and mitigation strategy. That's the whole goal, is to make sure that there's proper balance of the benefit/risk ratio and that the doctors who are prescribing the products know how to prescribe them and the patients that are using them know how to use them and so forth.

BY MR. CRAWFORD:

Q. Right. So that's one of the objectives of a REMS program. Right?

A. Correct.

Q. Is for doctors to know how to properly use the drugs and what the risks are. Right?

A. Correct.

Q. But before, for some of these drugs, when this generic OxyContin was approved, for instance, there was no REMS program for it. Correct?

A. I'm not certain.

MS. HILLYER: Objection to form.

THE WITNESS: Yeah. I'm not certain. The timeline's really meshed

together for me.

BY MR. CRAWFORD:

Q. Well, REMS only came into effect in 2007 when the FDA could require. Right?

A. Well, single shared REMS became effective in 2007. I'm not certain if there was other REMS that were in effect prior to that.

Q. Right. I think under subpart H, the FDA could require a risk management plan, which is kind of a precursor, but only as part of the approval process. Right?

A. For a brand product. Correct.

Q. Well, for generic products, too. Right?

A. Yeah. Again, that's something I'm not very familiar with.

Q. REMS can apply and do apply to generics. Right?

A. Yes.

Q. And in fact, the current REMS in place for the transmucosal opioid products and the extended release and the immediate release products all have REMS programs. Right?

A. I believe so, yes.

Q. And those apply to all generics in those categories. Right?

A. Yes.

Q. So my question is, is prior to these REMS programs, which are mandatory. Right?

A. Right.

Q. And each company submits its own REMS consistent with what the FDA wants for the class. Right?

A. So each company has to submit the approved REMS -- the FDA approved REMS to its application. Yes.

Q. That has to get approved as being in conformity with what they want. Right?

A. Yes.

Q. So before REMS were required, the immediate release, for instance, didn't have a REMS until 2018. Right?

A. I'm not --

MS. HILLYER: Objection to form, calls for speculation.

THE WITNESS: Yeah. I'm not certain.

BY MR. CRAWFORD:

Q. But recently. Right?
A. I'm not certain on the timelines.
Q. So before the approval of -- Teva's got immediate release opioid products they sell. Right?
A. I believe so.
Q. Okay. So before the approval of the REMS, and my question is, is could Teva, is there anything in the regulations that would have prohibited Teva from communicating with doctors if they became aware that doctors may not have been aware of the risks of opioid products or they were using Teva products or -- or proper use, that Teva could communicate with doctors consistent with its label, safety and use information?
MS. HILLYER: Objection to form.
THE WITNESS: If you could break that down for me.
BY MR. CRAWFORD:
Q. Okay. So you mentioned REMS. I'm trying to find out like before the REMS.
Immediate release had the REMS program in 2018, I'll represent.

So before REMS was issued, and before a drug was subject to it, could a generic drug company like Teva communicate with doctors about safety information concerning its products, as long as it's consistent with its approved label?
MS. HILLYER: Objection to form on multiple levels, and assumes facts not in evidence is one of them.
THE WITNESS: That's just not the typical practice. I mean, a generic company doesn't communicate with physicians. A generic company makes available the products based on an NDA and a brand product.
So the generic companies aren't -- don't have salespeople. They're not going out and talking to doctors. They're writing -- I mean, they're manufacturing products. And in some cases, physicians will prescribe a brand, but if there's a generic available, it gets substituted either by an insurance company or a pharmacy. So

generic companies don't go out and speak to doctors.
BY MR. CRAWFORD:
Q. So -- but if a generic company becomes aware that its products are being misprescribed or misused, who is going to tell the doctor? Whose responsibility is it then if it's not the generic company's?
MS. HILLYER: Objection to form.
THE WITNESS: I'm not certain what you're asking. I mean, I think the FDA has oversight over the, you know, the drugs that are approved in the United States and they have postmarketing responsibility -- I mean, they put postmarketing responsibility on the brand companies, and FDA is aware of the same information. So generic companies would rely on the FDA to make such decisions, if there is additional steps which are required. In this case, assuming that's why the REMS were put in place.
BY MR. CRAWFORD:
Q. What if the FDA doesn't know? I

mean, isn't the manufacturer primarily responsible for the safety of its product?
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. Or is it the FDA that's primarily responsible for the safety of generic products?
A. Sorry, can you repeat your question?
Q. Who's responsible for the safety of generic products? Is it the generic manufacturer that makes them or is it the FDA? Or is it the brand?
MS. HILLYER: Objection to form.
THE WITNESS: I mean, FDA is responsible for approving safe and effective generic drugs. And manufacturers are responsible for manufacturing safe and effective generic drugs.
BY MR. CRAWFORD:
Q. Right. So -- but what if, after it's approved by the FDA, it turns out that the doctors aren't using the drugs, the generic drugs safely, they're overprescribing it or they don't

understand the safety risks.
Who's responsible for communicating with the doctors, in your view, the proper use and safety of the drug?
MS. HILLYER: Objection to form.
THE WITNESS: Each generic company is going to have the same information available to them that the FDA would have available to them. FDA would have the ability to see what's happening. And FDA would be the one to make such decisions, which again, in this case, I believe they did in putting a risk evaluation and mitigation strategy in place.
BY MR. CRAWFORD:
Q. Do you believe there's an opioid epidemic right now?
A. I'm not sure I have an opinion on it.
Q. There's certainly an opioid -- some kind of opioid crisis going on.
You understand that. Right?
A. I think there's an issue with

misuse of opioids. But I think if opioids are prescribed properly by physicians and used properly by patients and, you know, prescriptions are filled by a licensed pharmacist, then they are safe and effective as long as they're used according to the approved label that FDA has approved.
Q. And at what point did you personally become aware that they weren't being properly used?
MS. HILLYER: Objection to form.
THE WITNESS: I don't have any personal recollection of when.
BY MR. CRAWFORD:
Q. What if the company became aware they were being improperly used before the FDA learned it? Who's responsible for telling the FDA, one, and then who's responsible for trying to correct it at that point in time?
MS. HILLYER: Objection to form.
THE WITNESS: Can you repeat your question, please?
BY MR. CRAWFORD:
Q. Yeah.

So if the company learns about an abuse or misuse problem with its opioids, a generic drug company, who's responsible -- and the FDA doesn't know about it yet, who's responsible for alerting the FDA? First of all, let's break it down.
Shouldn't the generic company alert the FDA in its annual report on that safety issue, whether it knows it or not?
MS. HILLYER: Objection to form.
THE WITNESS: How would the company become aware of that information?
BY MR. CRAWFORD:
Q. Because the company -- I mean, the company -- the company sells the drug. Right?
A. Okay. The company sells the drug, yes.
Q. Right. So it's -- the company is currently aware that there's an opioid crisis. Right?
A. How would --
MS. HILLYER: Objection to form.
THE WITNESS: So how would the

company become aware that there was misuse and abuse with its product?
BY MR. CRAWFORD:
Q. Didn't the company try to develop or want to develop an abuse-deterrent opioid? You were involved in that. Right?
MS. HILLYER: Objection to form.
THE WITNESS: I wasn't involved in the development of abuse-deterrent opioids.
BY MR. CRAWFORD:
Q. Right. But you were involved in at least thinking about it from a regulatory standpoint and getting them approved. Right? You gave a talk on it. Right?
MS. HILLYER: Objection to form.
THE WITNESS: I didn't give a talk on abuse-deterrent opioids.
BY MR. CRAWFORD:
Q. I thought you did, with regard to the difficulties in getting them approved. Right?
A. That's incorrect.
Q. What was your talk about?

A. My talk was about GDUFA and other barriers. And I think you're referring to Gregg DeRosa's talk.
Q. Yeah, DeRosa.
But you were present for Mr. DeRosa's talk. Right?
A. I was present, yes.
Q. So you knew the company was developing abuse-deterrent opioids. Right?
A. Okay.
Q. So at some point the company must have known that opioids were being abused. Right?
MS. HILLYER: Objection to form.
THE WITNESS: As well as FDA.
BY MR. CRAWFORD:
Q. Okay. But I'm just asking at some point the company knew. Maybe it knew before the FDA knew. Correct?
MS. HILLYER: Objection to form.
THE WITNESS: But maybe it didn't know before the FDA knew as well.
BY MR. CRAWFORD:
Q. So my hypothetical is, if the FDA

did know before -- or the company knew of the abuse of its opioids that it was selling in the marketplace before the FDA, shouldn't it at least put that in its annual report, that there's a safety issue out there?
MS. HILLYER: Objection to form.
THE WITNESS: Again, we follow the requirements and we submit to FDA what's required to be submitted. The scenario that you're talking about just -- it hasn't happened and I've never thought about it before and I don't have an opinion on it.
BY MR. CRAWFORD:
Q. So don't you think, when the FDA tells you in the approval letter that you're supposed to follow 314.81, and 3148.1 -- .81 requires the company to report any safety issues that comes up during a year, you're saying that they don't have to put that in with regard to a knowledge of an opioid abuse?
MS. HILLYER: Objection to form.
THE WITNESS: Again, I think as we explained in pretty great detail

there, 314.80 and 314.81 are common for both NDAs and ANDAs and there are certain requirements for NDAs that aren't expected or required to be submitted for ANDAs.
BY MR. CRAWFORD:
Q. And that's your belief?
A. Correct.
Q. And so if the company becomes aware that doctors aren't properly prescribing their products, regardless of whether the FDA knows or not, if there's no REMS out there, shouldn't the company at least send something out or try to educate doctors in the proper use of their drugs?
MS. HILLYER: Objection to form.
THE WITNESS: Yeah. I mean, again, how would the company become aware of such information?
BY MR. CRAWFORD:
Q. They are aware that their products are being abused. Right?
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:

Q. We just went through that, because they're making an abuse-deterrent opioid. Right?
MS. HILLYER: Objection to form.
THE WITNESS: We just went through that. But I also said that when the products are used according to their prescribed labeling, when their prescriptions are written properly by the doctor, they're used properly by the patients and they're distributed and dispensed by a licensed pharmacist, that they're used effectively. So FDA is aware of the same information that companies are aware now about the misuse and illegal drug use of these products.
BY MR. CRAWFORD:
Q. So -- but you're saying if used properly.
You know that they're not being -- the company knows they're not being used properly. Right?
MS. HILLYER: Objection to form.
THE WITNESS: When they're --

when they're obtained illegally and not used according to the label, but that's not why Teva would make a product or other manufacturers do. They make products because FDA has determined them to be safe and effective. They're a very effective treatment for people who need management of pain for these types of things.

BY MR. CRAWFORD:

Q. So once -- when Teva learned that their products are being abused, don't they -- doesn't the company have some obligation to go out and try to tell doctors how to properly use their products?

MS. HILLYER: Objection to form.

BY MR. CRAWFORD:

Q. In your view?

MS. HILLYER: Objection to form. And now asked and answered about four times.

THE WITNESS: I'm not sure what else I could say further on this.

BY MR. CRAWFORD:

Q. Is there any -- in your view, as a person who has been in the regulatory industry over 20 years, that there's any regulatory prohibition for a drug -- for a generic manufacturer to go out, you know, when there's no REMS, to go out and educate doctors in the proper use of their drugs?

A. I'm not certain.

MS. HILLYER: Objection to form. We've been going about an hour.

MR. CRAWFORD: Do you want to take a quick break?

MS. HILLYER: Sure.

MR. CRAWFORD: All right.

THE VIDEOGRAPHER: Off the record, 1:38.

- - -

(A recess was taken from 1:38 p m. to 1:49 p m.)

- - -

THE VIDEOGRAPHER: We are back on the record at 1:49.

- - -

(Deposition Exhibit No.

Teva-Tomsky-11, Letter dated December 6, 2005, 4 pages, was marked for identification.)

- - -

MS. HILLYER: This is 11.

BY MR. CRAWFORD:

Q. Exhibit 11 we've marked, it's a December 6, 2005 letter to Teva Pharmaceuticals, attention Philip Erickson. It is from, again, Mr. Buehler at the FDA. And this again, no Bates number, it was pulled from the FDA website.

So Mr. Buehler is writing now, approving here oxycodone hydrochloride extended release tablets, 10 milligram, 20 milligram and 40 milligram. I believe the one we just read was the 80 milligram approval. So this is the generic OxyContin at the lower doses.

Would you agree?

A. Yes.

Q. And this gives us some clues.

Go to the third page.

Mr. Buehler writes, "You have notified the Agency of the district court's summary judgment dated June 25, 2004, in favor of

TEVA, dismissing the case on grounds of unenforceability of the three patents. The Agency...is aware of the June 7, 2005 ruling by the U.S. Court of Appeals for the Federal Circuit, affirming the Opinion and Order of the same district court in a related case, issued in favor of Endo Pharmaceutical (Endo). The Federal Circuit ruling, among other things, permanently enjoins Perdue, enforcing the '912, '042 and '295 patents.

"The decision on June 7, 2005, as well as the first commercial marketing of the product by Endo on the same day, triggered Endo's 180-day generic drug exclusivity period."

Skipping a bit, "Endo's 180-day exclusivity for this...product expired on December 4, 2005. Therefore, under Section 505," et cetera, et cetera, "your ANDA is eligible for full approval."

So it looks like there was -- you agree with me -- a patent litigation which was holding up the marketing of the drug at this time.

Do you agree with that?

MS. HILLYER: Objection, lack of foundation, calls for speculation.

THE WITNESS: It appears so.

BY MR. CRAWFORD:

Q. So it looks like, at least in view at this time of Mr. Buehler, that the decisions rendered in the district and court of appeals allowed Endo to start marketing the drug that they had an exclusivity period, because they were first to market, that expired and then Teva was free to start marketing its generic version.

Is that how you interpret this?

A. Yes.

Q. Again, this is subject to the reporting requirements of CFR 314.80 to .81 and 314.98 there in the middle. Correct?

A. Yes.

Q. Let's go to the next exhibit.

- - -

(Deposition Exhibit No. Teva-Tomsky-12, ANDA Approval and email dated June 03, 2016, Bates stamped TEVA_MDL_A_02922022 through TEVA_MDL_A_02922025, was marked for

identification.)

- - -

BY MR. CRAWFORD:

Q. We're marking Exhibit 12.

This is an ANDA approval from Carol Holquist over at the FDA to Actavis Laboratories Florida, Inc., attention Janet Vaughn, director of regulatory affairs, dated -- well, it looks like on the last page there is an email dated June 3, 2016 from Kevin Herkenham at the FDA to regulatory affairs US, indicating that the ANDA had been approved and attaching a PDF copy of the approval letter.

So they were notifying, at least Actavis here in your view, of the approval of this product, which was a hydrocodone bitartrate acetaminophen tablet. Right?

A. Yes.

Q. So that -- I'm trying to understand.

Is that -- that's Vicodin. Right? Generic Vicodin? Or Norco? Do you know what brand product that is?

A. I'm not certain.

Q. And I'm trying to collaborate or -- this is Actavis product, so we're talking 20 -- June 2016.

This is right about the time Actavis was acquired by Teva. Right?

A. Roughly.

Q. So this product came over from the Actavis group. Right?

A. It would appear so, yes.

Q. Do you know if this product is still being marketed?

A. I'm not certain.

Q. Take a look at Exhibit 2, which is that list again, on page 5. I just want to see if you agree that's the second product listed on page 5, which is hydrocodone bitartrate and acetaminophen tablets, class II controlled drug schedule.

MS. HILLYER: Objection to form, lack of foundation, calls for speculation.

BY MR. CRAWFORD:

Q. Do you think that's the same drug there?

A. It's possible, but I'm not certain.

Q. In 2016, there are 9,092,709 prescriptions of that drug in that year. Right?

A. It appears so, yes.

Q. So this represents, just looking through, by far, the biggest seller of a class II opioid product by Teva in 2016; is that right?

MS. HILLYER: Same objection.

THE WITNESS: Based on this document, it looks like it.

BY MR. CRAWFORD:

Q. So -- and it's close to a third of their total relative -- it's 9 million out of 14.6 million of their Teva class II opioid volume based on the second page. Right?

A. So I'm not certain, because the first page shows 30 million.

Q. That's all opioid products. I understand it that way.

And then the second page is just the class II -- Schedule II opioids. Right?

A. Again, I'm not certain. I'm not familiar with this report.

Q. Okay. Well, this generic hydrocodone bitartrate and acetaminophen tablet, that's a class II opioid.

You agree with me on that. Right?

A. According to this, yes.

Q. Are you aware if this is still being marketed, this drug?

A. I think you just asked me that. I'm not certain.

Q. All right. I'm sorry. My memory sometimes goes as far as what I've asked, so -- yeah. Okay, thank you.

Do you have any kind of knowledge as you sit here of what Teva's current best selling opioid, class II opioid is?

MS. HILLYER: Objection to form.

THE WITNESS: I do not.

BY MR. CRAWFORD:

Q. Let's go to the next document.

- - -

(Deposition Exhibit No. Teva-Tomsky-13, Letter dated February 6, 2004, 2 pages, was marked for

identification.)

- - -

BY MR. CRAWFORD:

Q. So we've marked Exhibit 13. Again, this is a -- the prior exhibit was TEVA_MDL_A_02922022.

This current one, again, pulled from the FDA website, so it's not Bates stamped.

This is a February 2004 approval for oxycodone hydrochloride tablets, 15 milligram and 30 milligram.

This is a generic Roxicodone. Right?

A. That's what it says, yes.

Q. Where does it say that?

A. In the third paragraph, middle to end of that third paragraph.

Q. Okay. That's good. Yep.

Again, approved pursuant to the CFR 314.80 to 81, and 314.98. Correct?

MS. HILLYER: Again, I'm just going to object to foundation, among other things. This doesn't even say that it's Teva.

BY MR. CRAWFORD:

Q. Well, Amide was acquired at some point by Actavis. Right?

MS. HILLYER: Objection to the extent it calls for speculation.

THE WITNESS: Yeah. I'm not sure.

BY MR. CRAWFORD:

Q. Again, Mr. Buehler is the one who gave the approval. Right?

A. He's the head of the Office of Generic Drugs, so he signs most of them, yes.

Q. Right. Okay. Let's go to the next exhibit.

Actually, not that one. Skip that.

So this one.

- - -

(Deposition Exhibit No. Teva-Tomsky-14, Letter dated June 25, 2007, Bates stamped TEVA_MDL_A_10604467 through TEVA_MDL_A_10604633, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. Right here we have a letter from Actavis. This is written by Jasmine Shah, VP, regulatory and medical affairs, to Mr. Buehler at the FDA.

This is Actavis submitting a supplement as a changes being effected to seek approval for a batch size scale-up from 110,000 to 3.5 million tablets for the 15 milligram strength.

And this would be for the same ANDA, 76-636, as the Roxicodone approval that we looked at. Correct?

MS. HILLYER: Objection to form.

THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. So that's a pretty hefty increase in batch size.

Would you agree with me on that?

MS. HILLYER: Objection. Sorry.

BY MR. CRAWFORD:

Q. From 110,000 to 3.5 million?

MS. HILLYER: Objection to form.

THE WITNESS: It's an increase in

more than ten times the original batch size, yes.
BY MR. CRAWFORD:
Q. And why does a manufacturer need to get approval for that type of increase in batch size?
A. I mean, the regulations are clear in terms of what types of changes need to be submitted to the FDA. So, again, if you're making any changes that have been previously approved by FDA, and it falls into different filing categories, either an annual report, in this case, a CBE supplement, or sometimes a prior approval supplement.
Q. And CBE can just be done unilaterally without preapproval.
They're just notifying the FDA of the change in case the FDA wants to intervene. Right?
MS. HILLYER: Objection to form.
THE WITNESS: Generally speaking. But typically a company would wait 30 days before implementing such a change.
BY MR. CRAWFORD:

Q. That's generally the practice. Right?
MS. HILLYER: Objection to form.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. All right. And then go to the third page. Down at the bottom in bold, it says, "This application may contain documentation bearing 'Amide Pharmaceutical Inc.' name. Please note that Actavis Totowa LLC has acquired all rights of Amide Pharmaceuticals Inc., since July 27, 2005."
So you'd agree with me that Actavis, at least some Actavis entity, had acquired the rights to this product after that date?
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. It looks like acquired Amide. Right?
A. Yes, it appears so.
Q. So again, do you know if this is a product that's being currently marketed by Teva?

A. I do not.
Q. I'm just trying to triangulate it here with the chart that we have.
If you look at page 8, would you --
MS. HILLYER: Of Exhibit 2?
MR. CRAWFORD: Yeah.
BY MR. CRAWFORD:
Q. There is an oxycodone hydrochloride tablet, generic Roxicodone, listed in the middle of exhibit -- page 18.
And it starts up in 2016, which, of course, is the year Actavis was acquired. Right?
A. Yes.
Q. So do you think this -- is this the same product as this NDA here?
MS. HILLYER: Same objections, lack of foundation, calls for speculation.
THE WITNESS: It's possible, but I'm not certain.
BY MR. CRAWFORD:
Q. Okay. Let's go to the next

exhibit.
- - -
(Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked for identification.)
- - -
MS. HILLYER: Sorry. What number?
MR. CRAWFORD: 14.
MR. JENSEN: 15.
MR. CRAWFORD: 15, sorry.
BY MR. CRAWFORD:
Q. This is TEVA_MDL_A_10602657. It is a Supplement History for oxycodone hydrochloride tablets, ANDA 076-636.
Would you agree with me that this is the supplement history for the Roxicodone ANDA that we've just looked at in the prior two exhibits?
MS. HILLYER: Objection to form.
Prior two, meaning 13 and 14?

MR. CRAWFORD: Yeah.
THE WITNESS: It appears to be.
BY MR. CRAWFORD:
Q. Okay. And so tell me what a supplement -- have you ever seen one of these reports before?
A. No.
Q. Do you know if there's any way to generate within Teva currently a report of all the supplement activity with regard to a particular drug?
MS. HILLYER: Objection to form.
THE WITNESS: Yeah. I'm not certain. I haven't seen it. And I'm not certain how it was pulled. It could have been manually put together.
BY MR. CRAWFORD:
Q. But you don't know for sure? You don't -- you don't know whether it was manually put together or generated somehow?
A. Yeah. I'm not certain.
Q. If you look at the last page, it's 12/12/17 is one of the dates for labeling CBE. So this looks like it was put together

fairly recently. And I'm just trying to find out if there's -- if you wanted, as the head of the US generics regulatory, a supplement history, how would you go about doing that?
A. I would ask the person who's responsible for this product to provide it to me.
Q. Is there an FDA contact log that you're aware of that the company keeps?
A. So there's -- typically, I would guess those documents or any FDA contacts would be saved -- actually, now they're just saved in email.
But prior to current practices, I think there was -- there was a -- hard copies that were kept in binders.
Q. So there's no database of FDA contacts that you're aware of?
A. No, not that I'm aware of.
Q. So it's just kept in people's email boxes, if they get one. And if you want to look it up, you've got to go through people's emails?
A. Correct. Sometimes that information would be kept in the global

regulatory affairs database. So it would just be a line item that there was a call with FDA on such and such a date and this is the contents of what was discussed. But I'm not sure if it would be in detailed form. You would have to pull the actual email to find that information.
Q. For the supplement submissions and contacts, is that information kept in kind of a single place in the company for each drug?
A. Sorry, can you repeat your question?
Q. Like for supplemental ANDAs and tracking them for purposes of keeping them in one place, is there a place where information like that is kept?
A. So again, all the information would be saved in the product shared drive. And then in the global regulatory affairs database, every submission that goes to FDA, as well as correspondence that come back to FDA, is entered and logged into that database.
Q. So there is a log of correspondence that goes back and forth?
A. Yes.

Q. And is that in like a database or something?
A. Yes. It's the global regulatory affairs database. It's called Global Insight.
Q. And so if you wanted to get all the written exchanges between the FDA for a particular drug, is there a way to kind of filter the database for that?
A. It's pretty difficult. I think I alluded to it earlier. The global regulatory database is pretty challenging to navigate and even get reports ran, so that's why teams wind up keeping a lot of their own manual tracking sheets. So it's possible, again, that this came from a manual tracking sheet that somebody was doing.
Q. All right. Let's go to the next document.
- - -
(Deposition Exhibit No. Teva-Tomsky-16, Periodic Adverse Drug Experience Report, ANDA: 076636, TEVA_MDL_A_11065997 through TEVA_MDL_A_11066038, was marked for

identification.)

- - -

BY MR. CRAWFORD:

Q. So we've marked Exhibit 16, which is a periodic adverse drug experience report for the reporting period March 1, 2017 to February 28, 2018. It's for ANDA 076-636.

Again, this would be the generic Roxicodone product that we have been discussing the past few exhibits. Correct?

A. Yes, it appears so.

Q. All right. This is called a PADER, right, P-A-D-E-R?

A. That's correct.

Q. And are these the reports submitted pursuant to Section 314.80?

A. That's correct.

Q. And this is -- now I guess an annual report at this stage of the marketing of the drug. Right?

A. That's correct.

Q. But it's not the annual report that's submitted for 314.81. Correct?

A. That's correct.

Q. That's a separate type of report?

A. Yes.

Q. And this pretty much just lists adverse events in prior 15-day reports and so on that were discovered throughout the year. Right?

A. That's correct.

Q. And then who -- let's see.

Is this report signed or verified by anybody in the company?

A. Yeah. I'm not certain. This is a report that's put together by the pharmacovigilance team, but I would think that there would be a cover letter on this at least.

Q. So it was prepared in Zagreb, right, in Croatia?

A. That's what it says, yes.

Q. And what group --

It's the Teva periodic reports and risk management center global patient safety and pharmacovigilance group there that put this together?

A. That's what it says, yes.

Q. This isn't a Teva USA company that put this together. Right?

MS. HILLYER: Objection to form, lack of foundation.

THE WITNESS: Yeah. I'm not sure who the legal entity is.

BY MR. CRAWFORD:

Q. But it's Teva. Right? It's a Teva company?

A. Yes.

Q. Are these reports generally, the PADER reports, signed or verified by the company when they're submitted as being accurate and true?

MS. HILLYER: Objection to form.

THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. And the annual reports are, too. They're signed and verified by the company. Right?

A. Yes.

Q. And who verifies the annual reports for the company?

A. Which annual reports are you referring to now?

Q. For the opioids.

A. Which annual report? Are you talking about 314.80 or 314.81?

Q. 81.

A. 314.81, the practice currently?

Q. Yes.

A. Because the majority of them would be signed off in India.

Q. I got it.

Is that by a Teva entity in India?

A. Yes.

Q. If you just go through the report here, page 5, reports with fatal outcome.

That looks like there are several cases of overdose and death. Right? Here on the second page, from this drug?

MS. HILLYER: I'm sorry, which page are we on?

MR. CRAWFORD: Page 6.

BY MR. CRAWFORD:

Q. Or potentially from the drug.

A. Allegedly, yes, it appears so.

Q. And moving on to page 17, there's a non-15-day report serious label. Two of them

are for addiction to opioids, drug dependence.
Do you see those two at the bottom?
A. Yes.
Q. So serious -- they're not reported within the 15 days because addiction is a side effect already in the label. Right?
A. Correct. That's my understanding.
Q. But it's considered serious.
Serious is a defined term of art. Right?
A. Yes.
Q. So serious means -- what does it mean, hospitalization, death or affecting pregnancy or something like that?
A. I'm not certain.
Q. So -- but addiction does fall whatever under regulatory definition of serious. Right?
A. It appears so, yes.
Q. And then moving on to --
MS. HILLYER: I'm sorry, objection to form on the last one.

BY MR. CRAWFORD:
Q. -- page 35, there is a report of some type of drug misuse here, where oxycodone at least was one of the drugs that the patient was taking. Right?
MS. HILLYER: Objection to form.
THE WITNESS: Which one are you looking at?
BY MR. CRAWFORD:
Q. The first one.
A. I see several drugs, including heroin, so...
Q. Right. And oxycodone is one of the drugs, too. Right?
A. Yes.
Q. Do you have any idea how many people who use heroin started on prescription opioids, what the statistic is on that from the CDC?
MS. HILLYER: Objection to form.
THE WITNESS: I do not.
BY MR. CRAWFORD:
Q. Would 80 percent surprise you?
MS. HILLYER: Objection to form.

THE WITNESS: I've never heard any of those statistics, so I'm not familiar with it.
BY MR. CRAWFORD:
Q. So the source says, "Spontaneous, health authority, patient-consumer."
That just means that this report came into the company, Teva, through either a healthcare provider or a patient or a patient family member. Right?
MS. HILLYER: Objection, lack of foundation, calls for speculation. He's testified these reports don't come through them.
BY MR. CRAWFORD:
Q. Where did this report -- does this source of the report listed here give you any idea what the potential source was of the report?
MS. HILLYER: Same objections.
THE WITNESS: Again, I'm not familiar with this report, how things are categorized, what this means. I have no responsibility for these or the team that

puts these together.
BY MR. CRAWFORD:
Q. But this is submitted to the FDA. Right?
A. Yes. And as we discussed earlier, the regulatory affairs team manages the new ANDA submissions and then the post-approval supplements and annual reports, but the pharmacovigilance team manages the drug safety reports.
Q. So they interface with the FDA directly on these reports?
A. Yes.
Q. Understood.
But do you know what a spontaneous report is, right, in the regulatory parlance?
A. Generally speaking.
Q. Okay. What's your understanding of a spontaneous report?
A. When a company receives or when anybody receives a report of an adverse event with a product.
Q. Let's go to the next doc.

Actually, hold on.
Well, okay, let's mark it.
- - -
(Deposition Exhibit No. Teva-Tomsky-17, Letter dated 07/11/2013, Bates stamped Acquired_Actavis_00677901 through Acquired_Actavis_00677905, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. Okay. We've marked Exhibit 17, which is Bates Acquired_Actavis_00677901.
It's an approval letter to -- for ANDA 079-046 dated July 11, 2013, written to Actavis Elizabeth LLC by Kathleen Uhl at the FDA, U-H-L. And it's granting final approval of the oxymorphone hydrochloride extended release tablet.
That's again generic Opana ER. Right?
A. Correct.
Q. And do you know if this drug is -- and I understand you've said that you don't know a lot of the drugs, but just personal

knowledge, do you know if this is a drug that is currently being marketed by the company?
A. I do not.
Q. Let's go to the next exhibit.
- - -
(Deposition Exhibit No. Teva-Tomsky-18, Letter dated August 17, 2011, Bates stamped TEVA_MDL_A_10662653 through TEVA_MDL_A_10662655, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. Again, this is -- we marked another approval letter here, TEVA_MDL_A_10662653. It is ANDA number 076-709 for the fentanyl transdermal system.
This again would be an approval letter for --
A. This isn't an approval letter, at least --
Q. You're right. It's approving -- it's submitting an electronic REMS. Right?
A. Correct.
Q. But this would have been for a

product that was approved. Right?
A. I mean, I'm not certain. I would have to go back and look at the entire history.
Q. Right. I could not find the approval letter.
But are you aware if Teva is currently marketing a fentanyl transdermal system?
A. I'm not certain.
Q. Or if it ever has?
A. I believe it has, but I'm not certain if it's currently manufactured or not.
Q. Let's go to the next document.
- - -
(Deposition Exhibit No. Teva-Tomsky-19, Letter dated 11/17/2017, Bates stamped TEVA_MDL_A_08981645 through TEVA_MDL_A_08981651, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. We've marked here a letter dated November 17 -- or received November 17, 2017. It's a letter to Janet Vaughn of Actavis

Laboratories FL Inc. It's from Vincent Samsone from the FDA.
So this is an approval letter for generic Abstral. Right?
A. That's what the letter states, yes.
Q. And that's a TIRF product, a transmucosal -- some type of transmucosal product. Right?
MS. HILLYER: Immediate release.
MR. CRAWFORD: Thank you.
BY MR. CRAWFORD:
Q. Immediate release.
A. It appears to say that on page 3.
Q. So again, do you know if Actavis or Teva has ever marketed this product and whether it's currently being marketed?
A. I'm not certain.
Q. Okay. Let's go to the next one.
- - -
(Deposition Exhibit No. Teva-Tomsky-20, Letter dated 2014.12.29, 4 pages, was marked for identification.)
- - -

BY MR. CRAWFORD:
Q. This is an approval letter for morphine sulfate extended release capsules.
I think it's for the brand name Kadian. Correct?
A. I am not certain by this letter.
Q. Do you know -- are you aware if Teva manufactures, markets or sells Kadian or a generic version of Kadian?
A. Yeah. I'm not certain.
Q. Is it possible that Teva currently manufactures Kadian for Allergan at this point in time?
A. I'm not certain.
Q. If Teva manufactured a product for another company who is the NDA holder or an ANDA holder and that company distributed it, who would be responsible for making the regulatory submissions on that drug?
MS. HILLYER: Objection to form.
BY MR. CRAWFORD:
Q. Do you know? Is there kind of a general rule?
A. It would have to -- it would be

dependent on what product the -- what application the product is being manufactured under.
Q. So if it was being manufactured under an NDA -- let's take a hypothetical.
So it was being manufactured for an NDA holder by Teva, who would be responsible for the regulatory submissions, the annual reports and PADERs?
A. So if it's being manufactured under the NDA, meaning the NDA holder would have filed a site change to, say, an ANDA holder, the information would be filed to the NDA.
Q. So that means the NDA holder is filing it with the FDA?
A. Yes.
Q. All right. Let's do this next document here.
- - -
(Deposition Exhibit No. Teva-Tomsky-21, Industry Meeting to Discuss Opioid Analgesics REMS, 7 pages, was marked for identification.)
- - -
BY MR. CRAWFORD:

Q. So we marked -- again, this didn't come from the Teva production, but it's called, "Industry Meeting to Discuss Opioid Analgesics REMS." It's Exhibit 21.
It's minutes of a meeting held January 25, 2017. It looks like it was attended by members of the FDA and other organizations, and then members of industry regarding opioid analgesics REMS.
Had you heard about this meeting occurring?
A. It's not familiar to me.
Q. I see that there's no Actavis or Teva attendee.
I'm just wondering why, if you know, why they didn't attend this meeting?
A. No, I'm not certain.
Q. Who was head of the REMS group there at the time at Teva?
A. Again, it would have been Kishore Gopu, who we discussed earlier.
MR. CRAWFORD: Take a minute or two, I think I'm almost done.
MS. HILLYER: Okay. We'll go off

the record.
THE VIDEOGRAPHER: Off the record, 2:28.
- - -
(A recess was taken from 2:28 p m. to 2:46 p m.)
- - -
THE VIDEOGRAPHER: We are back on the record at 2:46.
- - -
(Deposition Exhibit No. Teva-Tomsky-22, Email chain, top one dated 1/9/2017, Bates stamped TEVA_MDL_A_09655240 through TEVA_MDL_A_09655244, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. I just have one more document here to look at. It's TEVA_MDL_A_09655240.
It's an email chain, starting at least the last one at the top, Brenda Hunsberger to you and several others, dated January 9, 2017. "Follow-Up Meeting: Status Check - ANDA Holder

Fee Clean-Up. Attachments: All Teva Companies and Product ANDA numbers" in an Excel spreadsheet.

So this is just the email chain.

Can you tell me what this interchange was about, as you recall?

A. Sure. As I recall, under the Generic Drug User Fee Act, GDUFA II, FDA began charging a program fee based on the number of approved applications per company.

And there was three different buckets. There was small, medium and large. Anybody with more than 20 approved applications was considered to pay the large fee.

But it's not like each applicant holder had to pay a fee. For example, Actavis didn't have to pay and Teva and Watson. So you can claim all those companies under the Teva affiliate.

So the purpose of this was to make sure that we collected all the different applicants and put them under the bucket of Teva.

Q. So you can say that a family of related companies could be compiled together for

the purposes of calculating the fees.

You wouldn't have to have, like if you got 20 different ANDA holders that are all owned by the same company, you didn't have to pay 20 different fees. Right?

A. Yes.

Q. And so what you're doing here is you're trying to compile all the various legacy entities and the ANDAs that you hold and you're trying to get that list generated. Right?

A. That's correct.

Q. And did you successfully get that list?

A. Yes.

Q. And who's Brenda -- did Ms. Hunsberger send that list?

A. So she's no longer with the company. Currently it's done by someone named Megan Hughes.

Q. What department is she in?

A. It's in regulatory, it's called the regulatory information management.

Q. Are they based in Parsippany?

A. Currently she's based in Frazer.

Eventually, this position will be located in Parsippany.

Q. So this list that's attached is basically just a list -- I haven't attached it, it's a huge spreadsheet.

But to me, tell me if this is accurate, it's a list of all the Teva-related companies, including the Actavis entities, Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and drug name below each company.

Is that what's being compiled here?

A. Generally speaking, yes. This is a list that was downloaded from the FDA's website.

Q. So this was compiled from the FDA website or from an internal database?

A. Yeah. So this is a list that would have came from the FDA, then each company downloads that list and separates out all the different entities that they want to claim as being under one company.

Q. So was this part of the fee

process, was they gave you access to this, the FDA?

A. That's correct.

Q. Is the public able to download this?

A. Yes.

Q. So -- but who made the decision or figured out what entities were Teva-related entities? Was that Ms. Hunsberger's department?

A. No. It was a compilation of several people. We worked with lawyers as well to make sure that we were capturing all the Teva entities.

Q. And do you feel that this final list captured all the Teva entities accurately?

A. Yes.

MR. CRAWFORD: All right. That's all I have. Thank you.

THE VIDEOGRAPHER: Going off the --

MS. HILLYER: No. Stay on the record.

THE VIDEOGRAPHER: Okay. Sorry.

MS. HILLYER: Mr. Tomsky, I just

have one brief redirect.

- - -

EXAMINATION

- - -

BY MS. HILLYER:

Q. Earlier in response to Mr. Crawford's questioning, you were talking about conversations you had with an individual in Israel.

Do you recall that?

A. Yes.

Q. And you mentioned that the substance or the basis for those conversations was the product filings prepared for the US.

Do you recall that?

A. Yes.

Q. Were any of those products opioid products?

A. No. Because all the opioid products are manufactured in the US. And the Israel team had nothing to do with those.

MS. HILLYER: I have no further questions at this time.

MR. CRAWFORD: All right. Me

neither.

MS. HILLYER: Do we have to go off the record to swap?

THE VIDEOGRAPHER: Yep, please. Going off the record, 2:52.

- - -

(A discussion off the record occurred.)

- - -

THE VIDEOGRAPHER: We are back on the record at 2:53.

- - -

EXAMINATION

- - -

BY MR. GASTEEL:

Q. Good afternoon, Mr. Tomsky. My name is Ben Gasteel. I represent a group of plaintiffs in the state of Tennessee who are pursuing cases that are slightly different than the cases that Mr. Crawford had been asking you questions throughout the day.

I'm going to go -- I'm not going to spend as much time as Mr. Crawford did today, so hopefully we can get out of here relatively

quickly.

I'm going to do my best not to cover anything that Mr. Crawford covered, but there might be a little bit of overlap.

I want to begin, you testified earlier about giving a deposition last week in a case?

MS. HILLYER: Sorry, Ben, before you get too far into your questions, I just want to place some objections on the record --

MR. GASTEEL: Sure.

MS. HILLYER: -- as I know you probably expected.

So we did not -- or the key people relevant to working on the Tennessee case from my firm did not receive the cross-notice that you told me about today.

I understand that your firm was informed earlier this month about who should be on the notification list. Those people were not on the notification list. And then there was subsequent

correspondence later in the month where we told you that we did not cross-notice Mr. Tomsky in the Tennessee action and we objected to your questioning him here. And there was no response received from your firm.

So I understand that, you know, you and I talked earlier off the record that you guys believe you sent the cross-notice. Setting that aside, I'm going to allow you guys to go ahead with questioning Mr. Tomsky over our objection, both to the relevancy of his deposition and procedurally how we got to being here, but with the understanding that, you know, as the Tennessee case proceeds, to the extent you later seek to depose Mr. Tomsky, we're going to say that this was your opportunity to do that and we've now given you that -- and we'll give you the opportunity to do that.

MR. GASTEEL: So I'll just say very shortly in response that we think that we've properly cross-noticed Mr.

Tomsky in the deposition. And to the extent that, you know, we may need to talk to him again, we'll continue to reserve that right. But we're certainly here willing and able to ask him some questions today.

MS. HILLYER: Understood.

BY MR. GASTEEL:

Q. With all of that out of the way, Mr. Tomsky, you talked earlier today about giving a deposition last week in an opioid-related case.

Do you recall that?

A. Yes.

Q. Do you recall the name of the plaintiff in that case?

A. I believe it was Guevnos.

Q. I don't suppose you know how to spell that?

A. I could try. I think it's G-U-E-V-N-O-S.

Q. And do you know if that case was pending in federal or state court?

A. I'm not certain.

Q. Is Teva a defendant in that case?

A. I believe so.

Q. Was it a Teva product that the plaintiff took that resulted in that lawsuit?

A. Allegedly.

Q. Mr. Crawford had previously asked you some questions about the current opioid epidemic and crisis that's going on in this country.

Do you recall some of that testimony?

A. Yes.

Q. Can you clarify, because I wasn't sure about your testimony.

As VP of regulatory affairs of generics at Teva, you knew that there was a problem with abuse and misuse of prescription opioids throughout the country. Right?

MS. HILLYER: Objection to form.

THE WITNESS: I wouldn't say I necessarily agree with that statement.

Can you reword?

BY MR. GASTEEL:

Q. Well, do you believe that there is a prescription opioid epidemic in this country

right now?

A. I believe there is an opioid epidemic related to the misuse and illicit use of drugs.

Q. And that would include prescription opioids?

A. Prescription opioids when they're obtained not from a prescriber or healthcare professional or what have you.

Q. And that would be an example of an abuse or a misuse of a prescription opioid. Right?

A. Illicit misuse, yes.

MS. HILLYER: Ben, can you speak up?

MR. GASTEEL: Sure.

BY MR. GASTEEL:

Q. Did you ever try to educate yourself as to the reasons why there was large scale abuse and misuse of prescription opioids?

MS. HILLYER: Objection to form.

THE WITNESS: No, I did not.

BY MR. GASTEEL:

Q. Did you ever try to educate

yourself as to the places that were particularly prone to abuse and misuse of prescription opioids?

MS. HILLYER: Same objection.

THE WITNESS: No.

BY MR. GASTEEL:

Q. While working with Teva as the VP of regulatory affairs generics, did you investigate at all the amount of Teva-produced generic opioids that were filling prescriptions in this country?

A. No.

MS. HILLYER: Objection to the form.

BY MR. GASTEEL:

Q. Prior to joining Teva, do you recall having any knowledge about abuse and misuse of prescription opioids?

A. No.

Q. Did the companies that you worked for prior to Teva manufacture or produce prescription opioids?

A. So I believe Ranbaxy had applications for these products. Whether or not

they are actively manufacturing them or distributing them, I am not certain.

Q. But they had at least an NDA or an ANDA to make them?

A. They had an ANDA.

- - -

(Deposition Exhibit No. Teva-Tomsky-23, Email chain, top one dated September 11, 2013, Bates stamped TEVA_MDL_A_11584417 through TEVA_MDL_A_11584419, was marked for identification.)

- - -

BY MR. GASTEEL:

Q. I hand you a document that we'll mark as Exhibit 23.

MS. HILLYER: Take your time to look it over.

THE WITNESS: Okay.

BY MR. GASTEEL:

Q. Do you see that this is an email from Gary Buehler to a variety of people, including you, on September 11, 2013?

A. Yes.

Q. And the email is forwarding an email from the previous day.

Do you see that?

A. Yes.

Q. From a Mark Hendricks (sic) at the GPHA?

A. Yes.

Q. What is the GPHA?

A. The Generic Pharmaceutical Association.

Q. Is that a trade group that Teva is part of?

A. Yes.

Q. And do they help Teva monitor what's going on at the FDA?

MS. HILLYER: Objection.

BY MR. GASTEEL:

Q. With regard to generic medications?

MS. HILLYER: Objection to form.

THE WITNESS: They're a generic trade association and, sure, they help disseminate information that's relevant to the generic industry.

BY MR. GASTEEL:

Q. And do they lobby on behalf of the industry?

A. I believe so. It's outside of my area of scope, though.

Q. I'm going to go through the email that was forwarded to you. It was referencing a call that occurred on September 10, 2013.

Do you see that at the top of the email, sir?

A. Yes.

Q. Do you recall whether or not you were on this FDA call that this email summarizes?

A. I do not recall.

Q. Do you see that the first paragraph states that: The guidance focused on class-wide likely changes and due postmarket survey requirements for all extended-release and long-acting opioid analgesics intended to treat pain.

Did I read that correctly?

A. More or less, yes.

Q. And it says, "The FDA is invoking its authority to require safety labeling changes

and post market studies to combat the crisis of misuse, abuse, addiction, overdose, and death from those potent drugs that have harmed too many patients and devastated too many families and communities."

Did I read that correctly?

A. Yes.

Q. And that was attributed to -- that was a statement that was attributed to the FDA commissioner at the time, Dr. Margaret Hamburg.

Do you see that?

A. Yes.

Q. And then the email goes on to talk about a letter that was received by NDA and ANDA applicants.

Do you see that?

MS. HILLYER: Where are you looking?

THE WITNESS: Yeah. I'm not -- where are you?

BY MR. GASTEEL:

Q. So at the bottom it says there's a letter to applicant holders.

MS. HILLYER: The very last paragraph?
MR. GASTEEL: It's the last thing in the email above the signature block.
THE WITNESS: Okay.
BY MR. GASTEEL:
Q. Do you see that?
A. Yes.
Q. Do you know if Teva received the letter that was referenced in this email?
A. Either way. I mean, via this email itself they would have received this letter.
Q. And then the email goes on, I believe, in the fifth paragraph down, beginning, "A safety labeling change was instituted."
Do you see that?
A. Yes.
Q. And it goes on to talk about new requirements for a boxed warning of -- it says addition, but I think it's meant to say addiction, "abuse, and misuse, which can lead to overdose and death."
Do you see that?

MS. HILLYER: I think he's here.
THE WITNESS: Oh, okay.
Yes.
BY MR. GASTEEL:
Q. Do you recall when the FDA required these safety labeling changes?
A. I'm not certain.
Q. Do you know if Teva added that label to its generic opioids at that time?
MS. HILLYER: Objection to form.
THE WITNESS: Again, as I had testified earlier, I mean, we monitor the FDA's website for labeling updates and revisions and to keep our labeling in line with the branded drug or the reference listed drug holder.
BY MR. GASTEEL:
Q. And according to this email, Teva would have at least had knowledge as of September of 2013 that the FDA commissioner thought that there was an opioid crisis of misuse, abuse, addiction, overdose and death. Correct?
MS. HILLYER: Objection to form.
THE WITNESS: Sorry, can you

repeat your question?
BY MR. GASTEEL:
Q. Sure.
It says, according to this email, Teva would have at least had knowledge as of September of 2013 that the FDA commissioner thought there was an opioid crisis of misuse, abuse, addiction, overdose, and death. Correct?
MS. HILLYER: Same objection.
THE WITNESS: Yes.
- - -
(Deposition Exhibit No. Teva-Tomsky-24, Email chain, top one dated 11/1/2013, Bates stamped TEVA_MDL_A_03487762 through TEVA_MDL_A_03487773, was marked for identification.)
- - -
BY MR. GASTEEL:
Q. I'm going to hand you a document that we'll mark as Exhibit 24. And it's an email and attachment to the email. And this is an email chain from October 2013 regarding a citizen's petition filed by various groups.

Take as much time with this document, sir, my question is going to be whether or not you recall receiving this email.
A. I mean, it doesn't stand out to me that I recall immediately when we received it, but sure, I mean, I'm on the email.
Q. Any reason to doubt that you received it?
A. No.
Q. Do you recall the citizen's petition that's referenced in this document?
A. I do not.
Q. Just for the jury, sir, can you briefly describe what an FDA citizen's petition is?
A. Sure. So a citizen's petition is a petition that's filed by anyone, any citizen of the United States or advocacy group or what have you. It's opinions that are expressed and written to the FDA to take into consideration.
Q. And does Teva regularly track citizen's petitions that have been filed with the FDA?
MS. HILLYER: Objection to form.

THE WITNESS: Yes.
BY MR. GASTEEL:
Q. And do you take positions on citizen's petitions? In other words, does Teva file responses to citizen's petitions?
A. I would say generally speaking we don't. These are petitions that are filed to FDA for FDA to opine on. There may have been cases in the past where Teva has felt the need to respond to one, but generally speaking we typically don't respond to these citizen's petitions.
Q. Is it regulatory affairs that tracks these citizen's petitions?
A. So, at this time, it would have the regulatory intelligence and policy group.
Q. And who in the regulatory intelligence and policy group would have been responsible for tracking FDA petitions at this time?
A. It would be Gary Buehler or it was also Gina Elton who was a part of his team who is on this email.
Q. Great.

I want to flip to what I think is the second page of that document. It's the email from Gina Elton to a variety of people, including you, on Tuesday, October 29, 2013.
Do you see that?
A. Yes.
Q. And it says, "FYI -- this CP was on our Watch List."
Did I read that correctly?
A. Yes.
Q. Do you know what that reference to "on our Watch List" means?
A. No. I mean, I believe it has to do with products -- if we have a pending or approved products, therefore, we would want to look at any citizen's petitions filed for any of our pending or approved products.
Q. And then if you flip to the next page, the email kind of gives a brief summary of what the citizen's petition sets forth.
Do you see that?
A. Yes.
Q. And then I want to begin with the paragraph, it's kind of the last paragraph. It

says, "The CP opens with a discussion."
A. Okay.
Q. Do you see that?
And it says the CP -- and that's a reference to the citizen's petition. Right?
A. That's correct.
Q. "The citizen's petition opens with a discussion of the current status of the abuse epidemic and the current administration's policy towards this problem."
Did I read that correctly?
A. Yes.
Q. And then it goes on to detail some of the products that are referenced in there.
Do you see the sentence beginning, "Numerous other initiatives from other Federal agencies"? Or I'm sorry, the sentence that begins, "The CP then discusses the specific products."
A. Yes.
Q. And it says, "The CP then discusses the specific products, oxycodone ER, oxymorphone ER, and buprenorphine implant and the

decisions made by the FDA regarding these products."
Did I read that correctly?
A. Yes.
Q. And then it states, "While they applauded the oxycodone decision, they were highly critical of the oxymorphone and buprenorphine implant decisions."
Did I read that correctly?
A. Yes.
Q. And then they state, and then it goes on to state, "They state tat" -- I think it's supposed to be that -- "recent FDA actions indicate that the FDA is not acting in a manner that adequately reflects the urgency of the prescription drug abuse epidemic, and that the FDA is not optimally exercising its regulatory authority to enhance the Obama" Administration's policies.
Did I read that correctly?
A. Yes.
Q. And then it goes on to state that the applicants are seeking applications for opioids without abuse-deterrent properties should

not be approved and that the FDA should work with sponsors to gather and report the needed data to support new abuse-deterrent formulations.

Did I read that correctly?

A. Yes.

Q. What is your understanding of abuse-deterrent formulations?

A. Abuse-deterrent formulations, meaning that it's more difficult to abuse than normal, such as hard to crush, difficult to snort, things like that.

Q. And then do you see that the summary then closes with, "It is difficult to assess the overall impact on Teva. It will impact both the generic and brand opioid programs-negatively for the generics and positively for the brand."

Did I read that correctly?

A. Actually, I didn't see where you are.

Q. It's the two last sentences of that paragraph, sir.

A. Yes.

Q. Do you know why this citizen's

petition would affect the generic Teva business negatively?

A. Again, without reading the petition, I'm not certain.

Q. And then is it because at that time Teva did not manufacture any abuse-deterrent formulations of generic opioids?

MS. HILLYER: Objection to form, calls for speculation.

THE WITNESS: Yeah, I'm not certain.

BY MR. GASTEEL:

Q. Are you aware of any generic opioids that Teva was producing then or has ever produced, marketed and distributed that have abuse-deterrent properties?

MS. HILLYER: Objection to form.

THE WITNESS: I don't believe so.

BY MR. GASTEEL:

Q. Will you flip to -- I'm sorry.

Go back to the first page of the email.

And then do you see that it attaches the FDA opinion granting in part and

denying in part this citizen's petition?

A. Where are you?

Q. It's on the attachments line of --

A. Oh, okay.

Q. Do you see that?

A. Yes.

Q. And then if you flip to the attachment, which I've included in your Exhibit 24, you'll see the FDA decision.

Do you see that?

A. Yes.

Q. Will you flip to the second page, and it says "Background"?

A. Yes.

Q. And it begins with, "Abuse and misuse of prescription opioids is a public health epidemic."

Did I read that correctly?

A. Yes.

Q. So it sounds like you disagree with the FDA that abuse and misuse of prescription opioids is a public health epidemic.

Do you disagree with that

statement?

MS. HILLYER: Objection to form.

THE WITNESS: Sorry, can you repeat your question?

BY MR. GASTEEL:

Q. Do you agree or disagree with the statement in this FDA ruling that "Abuse and misuse of prescription opioids is a public health epidemic"?

A. I agree with that.

Q. And that's going as far back as 2013. Right?

A. That's when this is from, yes.

Q. And it says, "According to the Centers for Disease Control and Prevention... sales of prescription opioids in the United States quadrupled from 1999 to 2010."

Did I read that correctly?

A. Yes.

Q. "Overdose deaths involving" those "products increased commensurately over the same period, from 4,030 to 16,651."

Did I read that correctly?

A. Yes.

Q. "By 2010 prescription opioids were involved in more than 75 percent of all prescription drug-related overdose deaths."

Did I read that correctly?

A. Yes.

Q. Do those numbers trouble you, sir?

MS. HILLYER: Objection to form.

THE WITNESS: I've never considered those numbers before. I never thought about it.

BY MR. GASTEEL:

Q. Well, as you're presented with them today, do those numbers trouble you?

MS. HILLYER: Same objection.

THE WITNESS: Again, I don't have an opinion on it.

BY MR. GASTEEL:

Q. Will you flip to the next page, beginning with section A, "Abuse-Deterrent Opioids."

A. Okay.

Q. And it says, "FDA considers the development of opioid analgesics with

abuse-deterrent properties to be a public health priority and supports that priority in several ways."

Did I read that correctly?

A. Yes.

Q. Did Teva also think that abuse-deterrent properties was important -- was a public health priority in 2013?

MS. HILLYER: Objection to form.

THE WITNESS: I'm not certain.

BY MR. GASTEEL:

Q. But at that time it was not manufacturing any opioids that had abuse-deterrent properties. Correct?

MS. HILLYER: Objection to form.

THE WITNESS: I don't believe so.

- - -

(Deposition Exhibit No. Teva-Tomsky-25, Email chain, top one dated 1/14/2014, Bates stamped TEVA_MDL_A_10197053 and TEVA_MDL_A_10197054, was marked for identification.)

- - -

BY MR. GASTEEL:

Q. You've just been handed a document that we have marked as Exhibit 25. And it's an email from January 2014 from Gary Buehler to a variety of people, including you.

Do you see that?

A. Yes.

Q. And it is also forwarding on an email from Gina Elton from January 13, 2014.

Do you see that?

A. Yes.

Q. And then the email from Gina Elton on Monday, January 13, 2014 has another one of these tables that we saw in the previous document.

Do you see that?

A. Yes.

Q. And it has formulated or formatted it in the same way, and it again is tracking another citizen's petition that has been filed with the FDA. Right?

A. Yes, it appears so.

Q. And then this one is from the Pharmacists Planning Services is the entity that

filed the citizen's petition.

A. Yes.

Q. And then the email from Mr. Buehler to you and a variety of other people on January 14, 2014 summarizes the citizen's petition.

Do you see that?

A. Yes.

Q. And do you see the last -- I'm sorry, the second to last paragraph, it says, "It is clear that this CP is a protest by a highly principled organization against the approval of Zohydro ER because it did not contain abuse-deterrent technology."

Did I read that correctly?

A. Sorry, I didn't follow where you are.

Q. Sure. It's the third paragraph there, beginning "It is clear."

A. Yes.

Q. And then Mr. Buehler -- am I saying his name correctly?

A. Yes.

Q. It's like the character in the

film?
A. Yes.
Q. He closes that paragraph with a claim that "Drug abuse in this country is an epidemic."
Did I read that correctly?
A. Yes.
Q. "I do not believe that abuse-deterrent products will solve the problem, but they would certainly be a start in addressing the impact of this problem."
Did I read that correctly?
A. Yes.
Q. Do you share that view, that abuse-deterrent products will be a start in addressing the impact of the drug abuse in this country that Mr. Buehler was describing in this email?
MS. HILLYER: Objection to form.
THE WITNESS: I haven't thought about it.
BY MR. GASTEEL:
Q. And then he closes that, "This CP should not impact Teva."

Do you see that?
A. Yes.
Q. Do you know why he thought that this particular citizen's petition was not going to impact Teva?
A. I'm not certain.
Q. Do you know how often you receive these emails about citizen's petitions from the FDA?
A. So when Gary was here, we'd receive them quite regularly. But since Gary has left, I would say they're few and far between. Although the legal team has started taking over the responsibility for circulating these.
Q. Okay. And best guess, about how often do you receive these types of emails about citizen's petitions at the FDA?
MS. HILLYER: Objection to form.
THE WITNESS: Roughly a couple times a month maybe.
- - -
(Deposition Exhibit No. Teva-Tomsky-26, Email dated November 21, 2017, Bates stamped TEVA_MDL_A_11731225

through TEVA_MDL_A_11731228, was marked for identification.)
- - -
BY MR. GASTEEL:
Q. Do you see that -- this, sir?
This is an email that you sent on November 21, 2017 to a variety of people I assume at Teva. Correct?
A. Yes.
Q. And with the subject "FDA issues guidance on development of generic abuse-deterrent opioids."
A. Yes.
Q. And it says, "All, Please see below. Attached is the guidance. I have not" reviewed yet, "but we will do so. Wanted to share with everyone ASAP."
Did I read that correctly?
A. Yes.
Q. So when this came out, you thought that it was important to share to some of your team over at Teva. Correct?
A. Sure. Any time any new guidances come out from FDA, again, as the regulatory team

is the liaison between FDA and the company, I send out similar emails for any guidances that are issued.
Q. Sure. And then you also included the statement from the FDA commissioner, Dr. Gottlieb. Right?
A. Yes.
Q. Is Dr. Gottlieb still the FDA commissioner today?
A. For probably another couple of weeks maybe.
Q. And the statement begins, "As we continue to confront the staggering human and economic toll created by opioid abuse and addiction, we're focused on taking actions that reduce the scope of new addiction by decreasing unnecessary exposure to opioids."
Did I read that correctly?
A. Yes.
Q. Did you agree when you forwarded this testimony or this statement on to your colleagues at Teva that there was a staggering human and economic toll created by opioid abuse?
MS. HILLYER: Objection to form.

THE WITNESS: I didn't think about it.
BY MR. GASTEEL:
Q. And then again, this is talking again about abuse-deterrent formulations of prescription opioids. And in the second paragraph beginning with abuse with -- "Opioids with abuse-deterrent formulations."
Do you see that?
A. Yes.
Q. His statement says, abuse -- "Opioids with abuse-deterrent formulations...are intended to make certain types of abuse, such as crushing a tablet to snort or dissolving a capsule to inject, more difficult or less rewarding."
Did I read that correctly?
A. Yes.
Q. Was that a concern because the current versions of opioids on the market could be easily crushed or snorted or injected? Is that part of the reason why the FDA is pushing for the development of abuse-deterrent formulations of prescription opioids?

MS. HILLYER: Objection to form.
THE WITNESS: I believe so.
BY MR. GASTEEL:
Q. And will you flip to the second page of his statement.
And there's the first full paragraph on that page beginning, "Transitioning from the current market."
Do you see that?
A. Yes.
Q. His statement says, "Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit."
Did I read that correctly?
A. Yes.
Q. Did you agree with his statement, that a meaningful public health benefit could be obtained by moving to abuse-deterrent property prescription opioids, as opposed to the conventional opioids that have dominated the market for the last several years?

MS. HILLYER: Objection to form.
THE WITNESS: I didn't think about it.
BY MR. GASTEEL:
Q. And when the FDA commissioner in this statement references "dominated by conventional opioids," he's referencing the prescription opioids that Teva has been manufacturing for several years. Correct?
MS. HILLYER: Objection to form and calls for speculation.
THE WITNESS: He's referring to opioids that do not have abuse-deterrent properties.
BY MR. GASTEEL:
Q. And that would be the types of opioids that Teva has been manufacturing for several years. Correct?
A. Sure, yes.
Q. You recall today that Mr. Crawford had asked you a lot of questions about -- I believe it's Exhibit 2, which is the document that listed Teva's opioid products and its share of -- market share of prescription

opioids.
Do you recall that document and testifying?
A. Yes.
Q. As we review some of these documents about the FDA statements regarding prescription opioids abuse and misuse, does it concern you at all that Teva has made these conventional opioids that are the source of this problem, and continues to do so, without any abuse-deterrent properties?
MS. HILLYER: Objection to form.
THE WITNESS: No. These are FDA-approved products that when prescribed according to the FDA-approved label, and taking into consideration the FDA-approved warnings and precautions, and when patients use them as directed, and when licensed pharmacists dispense them as directed, these medicines still serve a medical need to patients who need them.
BY MR. GASTEEL:
Q. Sure. But Teva is aware that

there is large-scale abuse and misuse, in other words, there's large scale use that is outside of the process of people taking them as directed when a licensed pharmacist dispenses them pursuant to a valid prescription. Right?

MS. HILLYER: Objection to form.

THE WITNESS: Yes. And FDA is aware of that information as well, and that's why there's risk mitigation strategies put in place as well.

BY MR. GASTEEL:

Q. And those risk mitigation strategies have been in place for several years. Right?

A. Yes.

Q. And we've seen, at least as of 2017, the commissioner of the FDA, in statements that you've forwarded to your colleagues at Teva, is continuing to talk about the staggering human and economic toll created by opioid abuse and addiction. Right?

A. Correct. But FDA still hasn't pulled those products off the market yet.

Q. And then Teva continues to

market, sell and distribute those throughout the country, including in states like the state of Tennessee. Right?

A. I'm not certain, actually.

Q. You're not certain as to whether or not Teva continues to market, sell, distribute and produce prescription opioids throughout the country?

A. I don't know which products Teva is actively marketing right now, especially specific to opioids, and as well as whether or not they're sold in Tennessee or dispensed in Tennessee.

Q. Were you ever on an FDA advisory committee regarding Opana ER?

A. No.

Q. Do you recall whether or not -- do you recall -- let me back up.

Do you know what Opana ER is?

A. Yes.

Q. What is it?

A. Oxymorphone extended release.

Q. And that was a branded product that was manufactured by Endo Pharmaceuticals.

Right?

A. I believe so.

Q. And then there was a generic version of that product that Teva also produced. Right?

MS. HILLYER: Objection to form.

THE WITNESS: I believe so. Again, I'm not certain whether or not we manufactured it.

BY MR. GASTEEL:

Q. Do you recall anything specifically about the reformulation of Opana ER that included an abuse-deterrent property?

A. Vaguely.

Q. You don't recall anything specifically about that?

A. No.

Q. Do you recall that, at some point, Teva pulled an ANDA related to oxymorphone ER tablets that was pending in front of the FDA in and around 2017?

MS. HILLYER: Objection to form.

THE WITNESS: Pulled meaning withdrew?

BY MR. GASTEEL:

Q. Yes.

A. Nothing stands out in my mind about it.

MR. GASTEEL: Mr. Tomsky, I believe that's all the questions I have for you.

MS. HILLYER: I just have one follow-up.

- - -

EXAMINATION

- - -

BY MS. HILLYER:

Q. Mr. Tomsky, when you referenced that you received emails from Mr. Buehler concerning citizen's petitions, and you mentioned that you would receive them perhaps a couple of times a month, were those concerning all products, all generics?

A. Yes. Anything that Teva had pending or approved.

MS. HILLYER: Okay. I have no further questions.

THE VIDEOGRAPHER: Okay. That

concludes today's deposition. The time is 3:30 p.m.

(Witness excused.)

(Deposition concluded at approximately 3:30 p m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, SCOTT D. TOMSKY, have the opportunity to read and sign the deposition transcript.

____

ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Registered Merit Reporter and Notary Public

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 289, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SCOTT D. TOMSKY DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public